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Learning from the Investigation of Incidents in Primary Care

Stephen Rogers

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Department of Primary Care and Population Sciences, Royal Free and University College Medical School, University College London, London WC1E 6BT

ProQuest LLC
789 East Eisenhower Parkway
P.O. Box 1346
Ann Arbor, MI 48106-1346

Statement of originality

The material in this thesis is original and constitutes my own work

Abstract

Accident investigation is widely used to learn from adverse events occurring in industry. The conclusions of such investigations are typically used to inform the design and function of socio-technical systems and organisational management. This tradition is less well developed in healthcare, though evidence is growing that similar approaches may be applicable.

The first part of the thesis reports a systematic review and evaluation of methods for the investigation of incidents in healthcare with further work then conducted to pilot an approach in primary and community care settings. The second part of the thesis describes the application of the approach within the framework of a study designed to understand the problem of medication related admissions in older people. The research maps the epidemiology of the problem and then moves beyond it through depth investigations of individual cases.

The methods selected have provided an opportunity to understand the immediate and the contributory causes of adverse medication related events in older people. More particularly, the approach provided a framework for understanding general practice as a whole system, where there are interactions between people, processes and policies that can bring untoward consequences. This level of understanding of general practice identifies broader themes that characterise the organisation of primary care and point to areas for development that could bring substantial benefits to patients in the care they receive.

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Publications

Some of the thesis materials have been published elsewhere. Chapter 2 is developed from a chapter written for "Clinical Risk Management in Primary Care" and published by BMJ Books (Rogers, 2001). Chapter 3 appears in full in "The Investigation and Analysis of Critical Incidents and Adverse Events in Healthcare", published by the NHS Health Technology Assessment programme (Woloshynowych *et al.*, 2005) and provides the basis for a chapter in "Patient Safety. Research into Practice", published by the Open University Press (Rogers *et al.*, 2006). An example of the case study method investigated and described in Chapter 4 appeared as a peer reviewed article in the British Journal of General Practice (Rogers, 2002).

List of abbreviations

All abbreviations used in this thesis are listed here unless used only once in which case the abbreviation will be explained in the text. When an abbreviation appears in a non standard form in a figure or table, a definition will appear in an associated legend.

A&E	Accident and Emergency department
ADE	Adverse drug event
ADR	Adverse drug reaction
AIMS	Australian Incident Monitoring System
ALARM	Association of Litigation and Risk Managers
APSF	Australian Patient Safety Foundation
ASHP	American Society of Health System Pharmacists
CIT	Critical Incident Technique
CLR	Classificatory reporting
CMO	Chief Medical Officer
CMP	Clinical Management Problem
CRU	Clinical Risk Unit
CWS	Comparison with Standards
FMEA	Failure Modes and Effects Analysis
GMC	General Medical Council
GP	General Practitioner
ICU	Intensive care unit
JCAHO	Joint Commission on Accreditation of Healthcare Organisations
MRA	Medication related admission
MRP	Medication related problem
NHS	National Health Service
NPSA	National Patient Safety Agency
PAS	Patient Administration System
PMRA	Preventable medication related admission
OACM	Organisational Accident Causation Model
RCA	Root Cause Analysis

SEA	Significant Event Auditing
US	United States of America

Glossary

Technical terms are used in the thesis. Their use is consistent through the thesis and their meaning is explained here.

Accident	An unplanned event or sequence that results in undesirable consequences. An incident with specific safety consequences or impacts.
Administration error	An error made by a healthcare worker, carer or patient in the administration of a drug.
Adverse drug event	An injury from a medicine or from lack of an intended medicine.
Adverse drug reaction	Any unexpected unintended, undesired, or excessive response to a medicine
Analysis	The use of methods and techniques of arranging facts to: a) Assist in deciding what additional facts are needed b) Establish consistency, validity and logic c) Establish sufficient and necessary events for causes d) Guide and support inferences and judgements
Cause	An event, situation or condition which results or could result directly or indirectly in an accident or incident.
Consequence	The cumulative, undesirable result of an incident, usually measured in health or safety effects, environmental impacts, loss of property and business interruption costs.
Clinical incident	An unplanned event or series of events and circumstances that may result in an adverse clinical outcome. Near misses and accidents qualify.

Critical Incident	An unplanned event or series of events and circumstances that may result in an undesirable consequence. Near misses and accidents qualify.
Dispensing error	An error made by a healthcare worker when preparing or dispensing a drug.
Failure Mode and Effects Analysis	A hazard identification technique in which all known failure modes of components or features of a system are considered in turn and undesired outcomes noted.
Human Error	Any human action (or lack thereof) that exceeds some limit of acceptability where the limits of human performance are defined by the system. Includes actions by designers, operators, or managers that may contribute or result in an accident.
Human Factors	A discipline concerned with designing machines, operations and work environments so that they match human capabilities, limitations and needs.
Investigation	A detailed systematic search to uncover facts and determine the truth of the factors (who, what, where, when, why and how) of accidents.
Incident Investigation	The management process by which underlying causes of undesirable events are uncovered and steps are taken to prevent similar occurrences.
Incident Investigation Team	A group of qualified people that examine an incident in a manner that is timely, objective, systematic and technically sound to determine that factual information pertaining to the event is documented, probable causes ascertained and complete technical understanding of such an event is achieved.
Medication error	Any preventable event that may cause or lead to inappropriate medication use or patient harm when the medication is in the control of the healthcare worker or patient. Includes prescribing errors, dispensing and administration errors.

Medication management problem	Any hazard that may cause or lead to inappropriate medication use or patient harm at any stage in the prescribing, dispensing, administration, review or follow up of patients requiring medicines and extending to the systems and processes that underpin safe and effective medication management.
Near miss	An unplanned event or series of events and circumstances in which undesirable consequences were avoided by safety features or specific intervention
Prescription error	An error made by a healthcare worker in writing the dose, strength or specification of a drug for dispensing and administration.
Prescribing error	An error made by a healthcare worker in prescribing the dose, strength or specification of a drug, in prescribing a contraindicated drug, or failing to prescribe an indicated drug
Risk	A measure of economic loss or human injury in terms of both the incident likelihood and the magnitude of the injury.
Root Cause	A prime reason why an incident occurred. Root causes are often related to deficiencies in management systems.
Therapeutic failure	An adverse effect that could have been avoided had an indicated drug been prescribed for a patient with a particular condition or risk factor
Witness	A person who has information related, directly or indirectly to the accident or incident.

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1. INTRODUCTION TO THE THESIS

General practice is a setting that accommodates much of the business of the British National Health Service. It is a setting in which things can and do go wrong and where occasionally patients may be harmed. There is literature on aspects of general practice that may have a bearing on patient safety, but little systematic knowledge that can be related to modern theories of accident causation. In particular, the fundamental structural characteristics that determines the way that general practitioners interact with their patients and with other health professionals has not been considered from a patient safety perspective. The aim of the thesis is to begin to explore this domain.

Investigations of major accidents outside health care have led to a broad understanding of accident causation with less focus on the individual who makes an error and more on pre-existing organisational factors that provide the conditions in which errors occur (Reason, 1995). Early application of "human factors" methods in healthcare has shown that medical accidents share many important similarities with accidents resulting from breakdown of socio-technical systems in other settings. A central tenet of the human factors approach is that influences operating at the level of work environment, management and organisation of work have a significant if not profound effect on the human actors involved in the delivery of care. These insights from outside health care have informed the specific objectives that underpin the research design and layout of the thesis.

1.1 RESEARCH OBJECTIVES

To map and describe the principal methods applied in the investigation and analysis of critical incidents in health care. To discuss the overall adequacy of the methods and the implications of the review for their development and application in health care settings

The literature on the investigation and analysis of critical incidents in healthcare remains diverse and poorly integrated. In particular, there has been no effort to map and appraise different approaches to the investigation and analysis of critical incidents. In this research the principal methods applied in the investigation and analysis of critical incidents in health care are identified, then the contexts in which they have been applied, the technical details of their application, the formulation of the results, the cogency of recommendations and the overall adequacy of the methods are described. Finally, the implications for the development and application of methods for the investigation and analysis of critical incidents in health care are discussed.

To adapt a theoretically sound method for the retrospective investigation and analysis of critical incidents for use in primary care settings. To pilot the method and to develop guidance for its use in primary care.

Methods that involve the retrospective investigation and analysis of critical incidents are often used to understand patient safety issues in healthcare. Although methods such as critical incident technique and significant event audit have been applied and developed in primary care settings, these methods were considered inadequate for the purpose of this thesis. Opinion was sought amongst primary care stakeholders on the likely applicability of a theoretically developed approach using a human factors framework that had been used in other medical settings, to applications in primary care. A series of incidents in which patients were harmed, or could have been harmed were investigated using the method and guidance was developed for primary care use.

To implement an occurrence screening system to collect data from which to describe the epidemiology of medication related admissions amongst older people admitted to hospital. To document the characteristics of the patients affected.

Older people are more likely to suffer with chronic illnesses, tend to be taking more drugs, are more vulnerable to drug effects and may have greater difficulties with drug administration. Up to half of all medication related admissions in older people may be preventable and are accounted for by medication management problems emerging in

the primary care setting. A study is described in which a series of older people admitted to a district general hospital were assessed for medication related problems. The study describes the characteristics of older people who were admitted due to their medication related problems and according to the type of medication related problems. Patients where problems were thought to be potentially preventable comprised the study population for subsequent investigation of contributing causes.

To use a depth investigative method directed towards exposing the root causes of medication management problems in older people. Through case studies to identify the contexts and processes that are responsible for error producing conditions in primary care

Human factors psychologists emphasise the importance of distinguishing between so called "active failures" such as failure to prescribe, monitor, or administer drugs, and the "latent failures" such as communication difficulties, system failures and problems with management or organisational policy, that exist in any workplace and which provide the backdrop against which active failures more or less inevitably occur. The epidemiological work described is linked with in depth community based investigations, directed towards understanding the reasons that medication related problems have occurred, analysed against a human factors framework and using a grounded approach. Analysis provides information on issues of relevance to medication management and throws light on more general operating characteristics that affect patient safety in primary care.

1.2 THESIS PLAN

This thesis aims to explore from a patient safety perspective the fundamental structural characteristics that determine the way that general practitioners interact with their patients and with other health professionals. The focus is medication management and the research applies a systematic approach to identify the contexts and causative factors underpinning preventable medication related admissions.

Chapter 1 presents the research objectives and provides an outline of the thesis. Chapter 2 provides the background and the historic literature. Chapter 3 contains a systematic review of methods used in the investigation and analysis of critical incidents in healthcare and Chapter 4 describes further development and adaptation of one of the methods for the purpose of exploring patient safety in primary care. Chapter 5 is an account of an epidemiological study of medication related admissions that provides descriptive data on the study population. Chapter 6 draws on case studies of patients with preventable medication related admissions to describe the evolution of accidents and the operating conditions of general practice as the context in which they occur. Chapter 7 summarises the work and presents overall conclusions.

1.3 JUSTIFICATION FOR THE RESEARCH CONDUCTED

The rise of risk management in the National Health Service is part of a wider and growing interest in quality management and improvement, reflected in a succession of government and professional initiatives (Taylor, 1996). Adverse outcomes of medication management are a significant problem in public health terms (Leape *et al.*, 1991; Thomas *et al.*, 2000) and many may be preventable (Department of Health, 2000). The risk management approach involves identifying, analysing and controlling risk. A significant proportion of serious adverse drug events may be generated as a result of problems with medication management in primary care (Howard *et al.*, 2003). Serious outcomes can be identified as medication related admissions, but little work has been done to analyse the context in which they occur. Berwick (1996) argues that the key to improvement is to understand and address process. Other commentators emphasise the importance of complexity in organisational systems and attribute accidents to interactions between processes and the lack or failure of built in safeguards to retrieve situations when things go wrong (Perrow, 1984). The findings of the research should provide a guide for action that can improve quality and safety in primary care settings.

1.4 POLICY CONTEXT

A series of policy documents published by the Department of Health in the United Kingdom provide additional context to this research, whose objectives bridge themes of patient safety and medication use. An overview of these documents follows.

1.4.1 An Organisation with a Memory

This report was commissioned by Health Ministers from an expert group chaired by the Chief Medical Officer (Department of Health, 2000a). The brief was to review what was known about the nature and scale of serious failures in health care in the United Kingdom and the extent to which learning and improvement followed the occurrence of such events. The report includes sections describing the problem, approaches and examples of learning and improvement in this arena, an overview of systems in place in the National Health Service and recommendations for future developments.

Existing information sources on adverse events were described as "patchy and incomplete" and research on learning from failures in health care as "relatively sparse". The report draws attention to the concept of active failures and latent conditions and calls on the health community to move away from blaming individuals towards a broader view of organisational accidents that recognises and addresses deeper system level factors that can place patients at risk. The report also draws attention to the absence of a managed system to collect and analyse contemporaneous data on adverse events within the National Health Service. These findings informed the key recommendations to promote a culture within National Health Service organisations that encourages reporting and learning from adverse events and a proposal for a system for capturing and synthesising locally collected information to drive decision making and improvement work at a national level. The report also declares four priority aims for patient safety and one of these was to reduce by 40% the number of serious errors in the use of prescribed drugs, a theme picked up in subsequent policy documents (Department of Health, 2004a).

1.4.2 National Service Framework for Older People

This National Service Framework for Older People (Department of Health, 2001a) promotes four key themes that are relevant to the health and well being of older people. These are respecting individual needs directed towards maintaining independence, providing intermediate care to avoid unnecessary admissions to hospital, providing evidence based specialist care, to include developments in the management of stroke, falls and mental health problems in older people, and promoting an active healthy life through relevant public health interventions. The management of medicines was considered fundamental to the standards operating across these areas. As well as dealing with medicines issues within the main National Service Framework, further details are provided in an accompanying booklet that focuses exclusively on medicines management issues (Department of Health, 2001b).

Medicines and Older People (Department of Health, 2001b) argues that many preventable adverse effects of medicines occur, that some medicines may be underused or not taken and that there is much wastage. Poorly managed medication changes on discharge from hospital, poor communication across the interface, inadequate repeat prescribing systems and dosage instructions, access issues and lack of involvement of carers could all contribute to medication management problems. The report advocates medication risk assessments for the most vulnerable and summarises interventions that might be expected to reduce medication related problems. These include prescribing advice and support, monitoring of treatment, prescribing reviews, and education and training of patients and carers. Special considerations in stroke, falls and mental health are highlighted and responsibilities are placed with Primary Care Trusts and hospitals to implement changes to assure medication safety and effectiveness.

1.4.3 Improving Medication Safety

In 2004 the Chief Pharmaceutical Officer returned to the target of reducing by 40% the number of serious errors in the use of prescribed drugs (Department of Health, 2004a). Improving Medication Safety explores the causes and frequency of medication errors, highlights drugs and settings that carry particular risks and identifies models of good practice to reduce risks. The medication process is reviewed, the risks of error during

the various stages are discussed and recommendations are made directed towards improved patient safety.

Active management and review of prescribing, double checking of dose calculations and shared treatment plans are advocated. The report also promotes the electronic care record and electronic prescribing systems as important technologies for reducing hazards. At the dispensing stage, formal checking systems should be introduced and effective communication with patients to ensure they understand their medications and how to use them, and all supported by appropriate training and assessment of competencies amongst dispensing pharmacists. Finally, accurate administration of medications, where health workers are involved, should include engagement of patients, clear procedures, double checking in high risk situations, use of information technology where relevant and safe storage to avoid retrieval and administration errors. The report carries specific sections on allergies, use of medicines in serious ill patients and children, and on reducing hazards of particular groups of medications that have been associated with problems in the past.

The concluding chapter addresses broad strategies for reducing the risk of medication related problems. These include consideration of the potential benefits of computerised prescribing and direct ordering systems, and of robotic dispensing systems. The issue of labelling and packaging is also dealt with in detail and a range of design solutions are advocated to avoid confusion between drugs with similar names and to reduce the frequency with which different drugs appear with similar packaging. The responsibility on hospitals to assure patients understand their drugs and that medication changes are communicated in an effective and timely manner is emphasised as are the broader governance issues including education and training and the need for continuous improvement based on reporting and learning from errors in healthcare settings.

1.4.4 Supporting People with Long Term Conditions

Policy documents directed towards supporting people with long term conditions were on outcome of the findings of Derek Wanless in his examination of health trends and factors that would determine the resources required to assure that the National Health

Service is able to continue as a comprehensive publicly funded service (Department of Health, 2004b).

The strategy for supporting people with long term conditions acknowledges the high prevalence of these conditions, the degree to which care has traditionally been reactive and the extent to which they have resulted in a heavy use of secondary care. About half of all medicines are not taken as prescribed, so attention to medication management is necessarily part of the strategy directed towards supported self care, disease management and case management, the three tiers of the health and social care model advocated for people with long term conditions. Overall it is hoped that early detection of morbidity, and effective medication management with good control can reduce short term crises and longer term complications, promote independence and prolong life (Department of Health, 2005).

There is little development of how to assure medication management is effective in the report, but the issues of building a delivery system and infrastructure to support the management of long term conditions is presented (Department of Health, 2005). This is to include improving information systems, increasing clinical engagement in the management of care, effective working between health and social care professionals and the employment of new professionals such as community matrons. The process of identifying patients who would benefit from additional inputs nevertheless draws on the number of medications taken as this is an indication of the extent of co-morbidity and of the complexity of care provision. In conclusion, the development of community support networks, increasing involvement of community pharmacists in medication management and increasing efforts to support the education and empowerment of patients and their carers, should it is hoped, lead to better outcomes for patients and reduce demands on acute hospital care.

2. HISTORICAL OVERVIEW AND ASSOCIATED LITERATURE

This chapter provides a broad overview of literature relevant to the thesis. The emergence of clinical governance in the British National Health Service is discussed followed by a detailed consideration of general practice as a risk environment for patients receiving care, with relevant examples. Detailed consideration of the literature as it pertains to particular original studies is deferred to the relevant chapters.

2.1 CLINICAL GOVERNANCE AND THE NATIONAL HEALTH SERVICE

2.1.1 Quality and safety in the British National Health Service

The early days of the National Health Service were dominated by the need to secure suitable buildings, equipment and staff. This was the structural fabric required to deliver health care effectively. Few systems were in place to monitor individuals or organisations and quality was closely linked with the concept of professionalism (McLachlin, 1976). Medical audit took place, typically driven by professional organisations, but it was not until the White Paper, "Working for Patients" that medical and later clinical audit became a requirement for staff working in the NHS (Department of Health, 1989).

Observations that the benefits of research were slow to become part of routine practice (Eddy, 1982) yielded to an evidence based medicine movement (Evidence Based Medicine Working Group, 1992) emerging in North America, but rapidly becoming international in its application. The concept of clinical effectiveness gained widespread acceptance within the health professions, and stimulated activity in producing guidelines and protocols to improve clinical decision making (Grimshaw and Russell, 1993a; Grol, 1995) and subsequently linked hand in hand with audit (Baker and Grol, 1998).

The concept of clinical governance was introduced in 1998 and implementing clinical governance became a statutory duty on National Health Service Trusts. Clinical governance provided a framework "through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence will flourish" (Department of Health, 1998). This represented an endorsement of the ideas of whole system quality improvement, which was becoming increasingly influential in healthcare settings (Berwick, 1996).

2.1.2 Emergence of risk management

The main impetus for the development of clinical risk management in the United Kingdom was the rising incidence and costs of litigation for clinical negligence against healthcare organisations. More recently the substantial human costs of clinical incidents has become an equally important driving force for clinical risk management (Vincent and Robertson, 1993). Until the late 1980s, no National Health Service organisation had a formal risk management function. Many had some of the components of risk management in place, but the essentials of risk management – linked processes for identifying, analysing and then controlling risk – were absent. However, in 1995, the establishment of the Clinical Negligence Scheme for Trusts and the introduction of national standards for risk management made it a national requirement that NHS Trusts should have such systems in place (Walshe, 2001).

Risk management involves balancing the costs of risk against the costs of reducing risk. The process of risk management thus involved identifying, analysing and controlling risks. In 1998, Walshe and Dineen noted that most Trusts had some form of clinical incident reporting in place and that they captured a substantial set of information about each clinical incident (Walshe and Dineen, 1998). The great majority of Trusts had a system for filtering out the most serious and urgent incidents and subjecting them to some form of senior clinical and managerial review. However few Trusts followed any established method of investigation, relying primarily on clinical experience and common sense approaches to analysing risks (Walshe and Dineen, 1998).

2.1.3 Medication safety

Drug therapy is a key component of modern medical care and prescribed medicine is the most frequent treatment provided in the National Health Service. General practitioners in England prescribe more than 600 million prescriptions every year and hospitals issue about 200 million scripts (Department of Health, 2004). Medication management is a multidisciplinary process, beginning with prescribing, includes dispensing by a pharmacist and then the administration of the medication by the patient, a carer or a nurse.

Although most drug treatment is safe, errors can occur at any stage in the pathway (Green *et al.*, 1998; Britt *et al.*, 1997). Most errors do not lead to ill effects, but some can be serious or fatal. Hospital discharge, communication across the interface, prescribing of repeats, dosage and administration arrangements are all known to be vulnerable to error (Department of Health, 2001b).

In the United Kingdom considerable focus has now been brought to the matter of preventable medication related incidents by the Department of Health and the National Patient Safety Agency. Targets have been set for reducing medication related errors and avoidable adverse events across the National Health Service, including reducing by 40% the number of serious errors involving prescribed drugs (Department of Health, 2004).

2.2 GENERAL PRACTICE AS A RISK ENVIRONMENT

The majority of contacts in general practice are for minor, self limiting illnesses, but practitioners also provide ongoing care to chronically ill patients with complex needs, they diagnose serious disease at first presentation, respond to calls for assistance in life threatening situations and manage preventive care. Recent years have witnessed unprecedented changes in the environment of primary care. These have been

characterised by raised patient expectations and demand, increasing responsibility for providing a wider range of services and greater accountability to patients, professional groups and to primary care organisations (Department of Health, 1996; Department of Health, 1997; Department of Health, 1998).

Much important groundwork has been done to promote quality in primary care, with the last decade witnessing more demanding education and training requirements, widespread acceptance of audit and increasing use of clinical guidelines as tools to improve the quality of care. What is newer to healthcare professionals in this setting is the thinking that safety, like effectiveness, needs to be explicitly managed and monitored. Information is presented on adverse events associated with medical management in the general practice setting. Then factors that might explain the occurrence of such events are explored, before moving on to a discussion of approaches which might be adopted by individuals, or by organisations to help avert their occurrence.

2.3 ADVERSE EVENTS IN GENERAL PRACTICE

There is no single source of data that can provide information on the incidence of adverse events in the general practice setting. The principle sources of information are medical negligence claims, reviews of primary care deaths, significant event audits and experimental reporting systems, together with the literature on prescribing errors and adverse drug reactions. Each of these sources provides a selective view, but together they paint a picture of the kinds of things that can go wrong.

2.3.1 Analyses of completed claims

Medical negligence is proven when a patient suffers harm and it is shown that the harm has resulted from failure on the part of the defendant to act in a manner consistent with that of a "responsible body" of colleagues (Scott, 1995). The most serious cases of misadventure associated with clinical care in general practice are represented in the claims databases of the medical defence agencies. Delays in diagnosis and treatment

accounted for 45% of 409 completed claims against general practitioners in a series published by the Medical Defence Union (Green *et al.*, 1998) with adverse outcomes from medications or other treatments, accounting for about 25% of 790 claims in another series of completed claims (Green *et al.*, 1996).

The medical conditions for which diagnoses were delayed are largely predictable. Serious infections (meningitis, pneumonia, epiglottis and malaria) were the most common group (15%), then orthopaedic conditions including missed fractures, slipped epiphyses and disabling vertebral disc lesions (14%). Delays in diagnosing common cancers were next (11%), followed by delays in diagnosing appendicitis, pregnancy (ectopic or intra-uterine), diabetes and myocardial infarction. The drug groups most frequently associated with claims were steroids, antibiotics, contraceptives, anticoagulants, non steroidal anti-inflammatory drugs and opiates, with the last three drug classes associated with 53% of the deaths attributed to medication errors.

2.3.2 Reviews of primary care deaths

Hart and Humphreys (1987) examined the medical records of 500 deaths occurring in a defined population served by a single general practice over a 20-year period and found avoidable causal factors in 223 deaths (45%). Avoidable factors attributable to the patient were evident in 26% of all deaths, to the general practitioner in 9% and to the hospital in 2%. A similar exercise is described by Holden *et al.* (1998). In their series of 1263 deaths, avoidable causal factors were found in 682 (54%). As in the earlier study, avoidable factors attributed to patients were the most important (40% of all deaths), with factors attributable to general practitioners in 5% and factors attributable to the hospital in 6% of all deaths. These studies have methodological limitations as information is likely to be incomplete and the criteria for avoidable factors are "neither standardised nor reproducible" (Hart and Humphreys, 1987), but they still provide a useful overview of the scope for clinical risk management in primary care.

2.3.3 Analyses of significant events

Significant event auditing is an approach in which individual cases are discussed by health care staff, with a view to identifying factors that can lead to improvements in the delivery of care (Pringle *et al.*, 1995). The cases are selected on account of an occurrence that is considered to be significant (usually, but not necessarily adverse) and would include patients dying in the primary care setting, and other adverse incidents or outcomes (Pringle *et al.*, 1995; Berlin *et al.*, 1992; Robinson *et al.*, 1995).

Pringle *et al.* described a study involving some ten practices in Lincolnshire and ten in Manchester, participating in significant event audits over a year. Four hundred and eighty nine clinical events (50 events per practice per year) were recorded, with 177 selected for review. These included 41 cases with new cardiovascular disease events, 35 concerned with care of chronic diseases, 31 events in the care of patients with cancer (mainly around diagnosis), 15 related to contraception and women's health, 12 to suicide, attempted suicide, violent deaths and trauma and 13 related to infections including 4 of meningitis. Delays in diagnosis and treatment were represented in this series, a number of acute medical conditions where preventive care was questioned, cases where there were evident communication difficulties and some medication errors. Action points for improving care were identified for over half of the cases reviewed, ranging from exhortations to be more careful, plans for educational activity, through to the drafting of new practice protocols and policies.

2.3.4 Incident reporting systems

Britt *et al.* (1997) set up a monitoring system for documenting adverse or potential adverse events in Australian general practice. Five hundred and ten GPs from membership lists of research and professional groups were invited to participate and 297 (42%) agreed to do so. General practitioners were sent incident reporting forms and asked to provide details of "any unintended event, no matter how seemingly trivial or commonplace, that could have harmed or did harm a patient". The findings are interesting, in that of the first 805 reports received, 51% of reported incidents were related to pharmacological treatments, and 34% related to diagnostic errors. The reason for this relative over-representation of incidents related to pharmacological treatments (compared to other data sources) is open to speculation, but factors might include

selective reporting and familiarity with surveillance systems for reporting adverse drug reactions. The pattern does not seem to be due increased reporting of "near misses" with pharmacological therapy as 18% of incidents were associated with serious adverse consequences for patients (compared to 21% in the series overall).

2.3.5 Adverse drug reactions and prescribing errors

An adverse drug reaction is an unexpected, unintended, undesired or excessive response to a medicine (ASHP, 1998). Of those adverse reactions that do occur, the majority are known, often mild and might even be considered trivial in the context with which they occur. For example, in one general practice based study, Martys (1979) found that 41% of patients reported some sort of adverse reaction (mainly effects on the gastro-intestinal tract and central nervous system) when interviewed one week after starting a new drug. In contrast, Mulroy (1973) documented a patient initiated consultation rate of closer to 3% in a study of follow up consultations with iatrogenic illness (mainly drug associated). This series includes some more serious events including acute glaucoma with tricyclic antidepressants, gastrointestinal bleeding with aspirin, intrahepatic obstruction with chlorpromazine and severe facial herpes simplex in a patient on corticosteroids. Some of these adverse drug reactions might have been preventable, though the degree to which this might have been the case was not formally assessed.

A series of studies have been conducted with the objective of identifying potential adverse drug reactions in primary care through analysis of prescribing scripts. Shulman et al (1981) worked with local pharmacists, over a three-year period, to monitor potential adverse drug reactions (anticipated allergic reactions, drug interactions or medical contraindications) and prescription errors. A total of 64,406 items were dispensed on 33,593 NHS prescriptions and 86 potential adverse drug reactions were picked up. This approximates to about 3% of patients for whom prescriptions were offered, and while these errors were relatively rare, some could have had serious consequences (for example an asthmatic prescribed propranolol and two patients on mono-amine oxidase inhibitors prescribed sympathomimetics). A differentiation was made between potential adverse drug reactions and prescription errors, described as

medication errors where the dose or strength of a drug had been written incorrectly, information omitted, or wrong drugs prescribed. Prescription errors were detected in 76 prescriptions (a further 3%) and some of these could also have been dangerous.

A number of other studies using a similar approach have since been published. Rates of potential adverse drug reactions and/or prescribing errors for scripts issued in primary care and presented at community pharmacies in western healthcare systems have been in the range 0.5-6% (Caleo *et al.*, 1996; Stevens *et al.*, 1997; Westerlund *et al.*, 1999).

2.4 DETERMINANTS OF ADVERSE EVENTS IN GENERAL PRACTICE

The reasons why avoidable adverse events occur to patients are always complex. A short consultation with a patient might involve a number of decisions being taken, and the consultation itself is a mere segment of a patient care pathway which could involve diagnostic testing, follow up, initiation and maintenance of treatment, referral and liaison with secondary care. At every point there is a risk of error, and a variety of factors can have implications for the safety of the patient. Such factors may operate at the level of the individual health professional, in relation to the particular health care process, or as a feature of the organisation in which care is delivered.

2.4.1 Doctors' characteristics

The General Medical Council emphases the importance of the quality of professional relationships with patients alongside the more traditional expectations of doctors to provide high quality care and to maintain probity in professional matters (GMC, 1998). Similarly, in Tomorrow's Doctors (GMC, 1993), the importance of acquiring appropriate clinical knowledge and practical skills appears alongside the need for proficiency in communication skills. It is interesting to speculate on the relationship between these aspects of clinical competence and safety in medicine.

Sloan *et al.* (1989) published an important study in which the characteristics of doctors with favourable and unfavourable claims were compared. Doctors with more

prestigious credentials did no better than those with less prestigious credentials in any speciality, and there was no association with country of qualification, solo or group practice, or involvement in research or teaching. Levinson *et al.* (1997) studied the relationship between communication skills and malpractice claims amongst primary care doctors and surgeons. Although no relationships were noted amongst the surgeons, primary care physicians with claims were characterised by shorter clinic visits and particular modes of communication. In particular "claims" physicians used less orienting statements (for example explaining what was going to happen next), and less facilitating comments (asking opinions and checking understanding).

The literature is consistent in the respect that complaints about doctors are more usually about communication problems rather than issues around technical competency. While there is no study that directly addresses doctor patient communication and safety, there is good evidence that particular aspects of communication skills can affect patient satisfaction, adherence and co-operation with management plans. Doctors with appropriate communication skills are likely to be safer as well as more popular (Stewart *et al.*, 1999).

2.4.2 Factors influencing doctors' decision-making

There is a large literature on medical decision-making (Dowie and Elstein, 1998) and a selection of studies, which enquire into factors that can lead to physician error. Two studies of primary care doctors bring out some common themes.

Ely *et al.* (1995) interviewed 53 family doctors in Iowa, US. The data is based on in depth interviews in which physicians were asked to describe their most memorable error and the perceived causes. The investigators developed a classification of perceived causes and found these to fall within four groups; physician stress (being hurried or distracted), process of care factors (e.g. premature closure of the diagnostic process), patient related factors (e.g. misleading or normal findings) and physician characteristics (e.g. lack of knowledge). Often these were acting together, with physician stress relevant in 91%, process of care factors in 91%, patient-related factors in 72% and physician characteristics in 62% of the 53 errors.

Bradley (1992a) carried out another qualitative study, this one focused on uncomfortable prescribing decisions in British general practice. Seventy four doctors provided details of 307 incidents in which they had felt uncomfortable with their prescribing. Antibiotics, tranquillisers or hypnotics were the drugs most often involved. Reasons given for decisions taken were patient expectation, clinical appropriateness, factors related to the doctor-patient relationship and being led by preceding events. Logistic problems such as lack of time, a wish to avoid drug toxicity, a need to close the consultation, drug costs and seeking to avoid extra work also appeared, if less frequently.

As these studies are based on physicians' perceptions they cannot provide a basis for assessing the relative importance of various factors. However, they do show the importance of social and logistic influences on decisions taken in primary care. In particular, the environment in which the doctor works and the nature of the doctor-patient relationship can have a capricious influence on the decision making process.

2.4.3 Practice procedures

Practice policies and procedures for arranging appointments and follow up consultations, emergency care and home visits, communications with secondary care providers, the review of test results and the management of repeat prescriptions can have a direct influence on the risk of adverse events occurring to patients. Such problems were frequently identified as contributory factors to adverse events in significant event audit data (Pringle *et al.*, 1995) and in the Australian incident reporting study (Bhasale *et al.*, 1998).

Apparent failures of practice procedures also feature prominently in data on complaints made about general practitioners and the service they offer. Owen (1991) describes a series of 1000 complaints notified to the Medical Protection Society during 1976-88. About 50% of complaints arose in situations where complainants felt there had been inappropriate delay in diagnosis, treatment or referral and 30% of these occurred specifically as a result of a failure to carry out a home visit. A further 8% of complaints

were precipitated by errors in prescribing. Delays may result from poor communication with patients, or errors of judgement, but can also be introduced by poor administrative systems within practices (e.g. referral letters or test results being mislaid). The issue of dealing with requests for home visits continues to exercise the profession. General practitioners no longer have a contractual obligation to conduct home visits "unless medically indicated" but the effectiveness of assessment procedures used and the threshold for visiting could determine whether patients are put at risk (Norwell, 1999). Wrongly written prescriptions, which could not be dispensed, accounted for some of the prescribing errors, but also errors of dosage and drug and the prescription of contraindicated drugs.

2.4.4 Practice characteristics

There are considerable variations in the levels of development of practices in the United Kingdom and elsewhere (Baker, 1992; Ram *et al.*, 1998). Baker (1992) devised a development score based on a questionnaire assessment of equipment, staff, clinical activities, records, organisation, premises, availability and clinics and found a wide variation across three counties in England. In a multiple regression analysis he found that being a training practice, having a practice manager, a larger total number of patients, and a lower Jarman score for underprivileged areas was associated with higher levels of practice development.

However, research to date has shown no clear relationships between practice characteristics, their level of development and the quality of care they offer. For example, Ram *et al.* (1998) carried out a study of 93 GPs, who agreed to submit videotapes of their consultations. A range of practice characteristics were assessed and a validated instrument was used to assess physician performance (competence and communication skills). The authors of this study concluded that practice structure and clinical performance were not related and suggested that although each might effect particular patient outcomes, they need not be associated within individual practices. In another study, lower patient satisfaction was associated with increasing list size, shared patient lists and being a training practice, which suggests an inverse relationship between practice development and some aspects of quality of care (Baker, 1996).

Lower admission rates for asthma are to be found in practices whose prescribing rates suggests better preventive care and lower admission rates for diabetes in practices with better organised diabetic care (Aveyard, 1997; Farmer and Coulter, 1990) but no clear links have been demonstrated between admission rates and practice characteristics such as the number of partners, list size or staffing patterns (Giuffrida *et al.*, 1999). Another study of admission rates for chronic diseases also draws attention to the importance of socio-demographic and hospital, rather than general practice factors as determinants of hospital admissions, and similar conclusions are drawn in a study of admissions from 120 general practices in South London (Reid *et al.*, 1999).

Inevitably there will be relationships between some aspects of practice structure and whether the care offered is safe and effective. However, the huge variations in the way practices are organised, and the effects of individual as well as organisational factors on the quality of care make it hard or impossible to elucidate the relevance of individual practice characteristics in simple quantitative studies.

2.5 PREVENTING ADVERSE EVENTS IN GENERAL PRACTICE

A number of strategies have been adopted to help reduce the occurrence of unintended adverse events in general practice. Some operate at the level of the consultation between doctors and patients, while others relate more to the organisation and management of the practice. Some would be managed and promoted on a locality basis, for example at Primary Care Trust level, while others require promotion through medical school curricula or national frameworks.

2.5.1 The consultation

The consultation is central to the experience of general practice, with recent literature on the application of evidence based medicine adding to important earlier literature on the conduct, process and goals of the consultation. The consultation as the setting for

risk management is a new focus, but current developments in a number of areas are relevant and growth in the literature on this important issue is to be expected.

2.5.1.1 Clinical guidelines. Clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Field and Lohr, 1990). The potential for guidelines to affect the quality of patient care is considerable (Effective Health Care, 1994) and the acceptance of and familiarity with clinical guidelines is growing (Siwardena, 1995, Newton *et al.*, 1996). In a systematic review of evaluations of the 59 published evaluations of guideline implementation by a variety of means, all but four detected significant improvements in the process of care (Grimshaw and Russell, 1993b).

High quality evidence based guidelines are now available for many of common conditions that are managed in primary care (SIGN, 1996a; SIGN, 1996b; North of England Guidelines Development Group, 1998a; North of England Guidelines Development Group, 1998b). Their implementation might be expected to reduce acts of omission on the part of general practitioners, and to help prevent associated adverse outcomes for patients. Evidence based materials on the predictive value of various diagnostic manoeuvres are also important to the practising physician, who needs to make rational choices about test ordering or changing referral thresholds in order to avoid missing important diagnoses. A series of papers appearing in the "Journal of the American Medical Association" provide an excellent overview of the issues (Sackett, 1992; Badgett *et al.*, 1997; Margolis and Gadomski, 1998; Anand *et al.*, 1998).

2.5.1.2 Decision analysis. Formal decision analysis has typically been used in research settings, to combine data from other studies mathematically to determine optimal strategies for particular clinical situations. In formal decision analysis different diagnostic and management options are drawn out like the branches of a tree, with branches allocated probabilities corresponding to the likely benefits and risks of pursuing a particular course of action. The approach is becoming better known (Pauker and Pauker, 1977; Tomkins *et al.*, 1977; Tsevat *et al.*, 1991; Naimark *et al.*, 1994). Optimists hope that eventually there might be a library of computerised decision trees, which could be linked up with diagnostic codes in computerised records (Doubilet and McNeil, 1994). Greenhalgh and Young (1998) show how decision analysis can

contribute to the consultation with individual patients, but point out that the relevant information is often not readily accessible. For example, it is notoriously difficult to portray the risks and benefits of even commonly met problems and the way the information is presented (verbal, tabular or graphical presentations, leaflets, videos, web pages etc) can have a very significant effect on its meaning and impact (Elwyn *et al.*, 1999).

2.5.1.3 Computerised decision support. Various computer systems have been described which might aid clinical decision making, and some have been evaluated in research studies (Hunt *et al.*, 1998). Systems which provide prompts to encourage doctors to perform preventive procedures have delivered demonstrable benefits in the care of hypertension (Barnett *et al.*, 1983; McAlister *et al.*, 1986) and in cervical screening (McDowell *et al.*, 1989) and systems to improve the safety of prescribed drugs also show great potential. For example, in an American trial, a computer system designed to give advice on warfarin was shown to lead to better control than usual care (White *et al.*, 1987) and systems for supporting use of digoxin can reduce the risk of digoxin toxicity (White *et al.*, 1984). Diagnostic systems have been more disappointing, though their low impact has largely been attributed to a failure to utilise the systems rather than to the quality of the systems as such (Pozen *et al.*, 1984, Wellwood *et al.*, 1992).

Computers are widely used in general practice, though mainly to store and retrieve information and to simplify administrative processes like the organisation of appointments and the printing of repeat prescriptions (Social Surveys Limited, 1993). General practice computer software systems are now becoming increasingly sophisticated and a fully developed prescribing system will check the name of a drug against previous drug idiosyncrasies held in the patient record, against possible interactions with current medications and against conditions in the patient record for which the drug is contraindicated. Many systems will carry out simple calculations and compare individual measures with standards, or calculate risk scores from combinations of variables and computerised decision support in primary care may be an area due for further growth (Preece, 1990).

*2.5.1.4 **Shared decision making.*** Consumerism and increasing availability of information has shifted the emphasis of doctor-patient communication away from passive, more paternalistic transfer of information from doctor to patient (O'Connor, 1997). Shared decision making is said to sit somewhere between paternalism and informed choice and is increasingly advocated as the ideal model for treatment decision making in the medical encounter (Elwyn *et al.*, 1999; Deber, 1994; Charles *et al.*, 1997). Five steps are described; understanding patients views on treatment options, eliciting patients preferences, transferring technical information, weighing up risks and benefits then sharing the recommendation and/or affirming the treatment preferences (Elwyn *et al*, 1999). It has been argued that the key dimensions of communication represented in the shared decision making model, are the same as those which have been related to positive outcomes in empirical studies (Elwyn *et al.*, 1999). As yet there is no information to suggest that shared decision making will be associated with safer care, though it seems likely that the information sharing process and the associated patient empowerment could have a positive effect on risk avoidance. It has been suggested that a move towards "informed choice" could be a consequence of doctors behaving defensively. However the model provides more than a medico legal defence in the event a patient suffers harm as the communication strategies adopted are those more likely to be associated with constructive mediation between the parties (Stewart *et al.*, 1999).

2.5.2 Practice quality assurance

It is argued that the most appropriate model for assuring quality in general practice is one which is managed by individual practices on behalf of the patients they serve (Irvine, 1990). Risk management is explicitly one of the components of quality assurance activity in health services (WHO, 1989) and this section focuses on approaches advocated to assure the safety of the organisational systems in the primary care setting.

*2.5.2.1 **Addressing Complaints.*** A general practitioner who is a principal on the list of a health authority is subject to statutory obligations to "render to his patients all necessary and appropriate services of the type usually provided by medical practitioners" under their terms of service. In a survey carried out by Summerton

(1994) 98% of general practitioners reported having made changes to counter the risk of patients lodging complaints or taking legal action in response to perceived inadequacies in care. Such changes included lowering thresholds for referral, avoiding treating certain conditions, increased diagnostic testing and follow-up, reduced prescription of unnecessary drugs, increased screening, increased audit, more detailed note taking and more detailed explanations to patients. Following the Wilson Report (Department of Health, 1994) the highly adversarial complaints system involving service committee hearings was replaced by a two stage system, in which the first stage is an in house reconciliation procedure. The vast majority of complaints are now defused at the level of the practice (McKee, 1996). Such complaints can provide a good source of data for quality improvement activities (Pietroni and de Uray-Ura, 1994). For example, complaints can provide information on issues, which are relevant to patient satisfaction, and to the functioning of practice systems such as message taking and appointments. Indeed, the analysis of complaints has been advocated as a core component for clinical governance (Roland and Baker, 1999).

2.5.2.2 Death registers. Hart and Humpherys (1987) argued, "A retrospective search for avoidable factors in individual deaths is perhaps the most stringent form of self criticism available to any clinical team". In a similar exercise, Holden *et al.* (1998) developed a protocol that was shared across four practices. This group emphasised the educational value of the exercise and participating practices were examining deaths on an ongoing basis. One of the barriers to the systematic analyses of deaths is the lack of routine data on deaths occurring in practice, though providing a death register will not, on its own, result in improvements in the organisation of care (Stacy *et al.*, 1998).

2.5.2.3 Significant event auditing. The approach draws on the philosophy of the critical incident technique, originally developed and applied to the analysis of accidents in the aviation industry (Flanagan, 1954). A key difference between significant event auditing in general practice and the critical incident technique as originally described is the emphasis on drawing on the experience of a group of informants, and particular attention is given to managing the dynamics of the group, so individuals can openly discuss inadequacies in care. An external facilitator may be employed to good effect or the participants themselves may run the process. As in the critical incident technique, in significant event auditing "individual cases in which there has been a significant

occurrence" are analysed in a detailed way to ascertain what can be learned about the overall quality of care and to indicate changes which might lead to future improvements" (Pringle *et al.*, 1995). Some commentators advocate a structured enquiry into various areas including the immediate management of a case, preventive care, arrangements for follow up, interface and team issues and action points arising (Pringle *et al.*, 1995). Alternatively, the discussion is deliberately kept open and far reaching, with *post hoc* classification of findings into various categories (Berlin *et al.*, 1992). Whichever approach is taken, there is an assumption that the emotional engagement with issues of concern is an important motivating factor in subsequent delivery of change.

2.5.2.4 Audits of clinical care and administration. Medical audit as a strategy for quality assurance is well established in primary care (Lawrence and Schofield, 1993). A systematic review of the effect of audit and feedback on professional behaviour has demonstrated that the approach can lead to improvements in performance, especially with respect prescribing and test ordering (Balas *et al.*, 1996; Thompson *et al.*, 1999). Of course, audit and feedback should not be used generally for all problems, but should be targeted towards areas where the approach is likely to generate change (Thompson *et al.*, 1999). Pringle *et al.* (1995) attempted to compare the effect of conventional audit and significant event audit in 20 practices. Practices using conventional audit covered fewer areas of clinical care, but areas covered were done in greater depth. In their conclusions, the researchers suggest that conventional audit and significant event auditing should in fact be used as complementary approaches. Other advocates of significant event auditing now explicitly link the information gathering process inherent to the significant event audit to a conventional audit which serves as the implementation phase of a "double loop audit cycle" (Robinson *et al.*, 1995).

2.5.2.5 Continuous quality improvement. Continuous quality improvement is an approach to quality assurance, which is underpinned by a focus on the improvement of the systems required to deliver quality care. Positive outcomes are achieved by involving key organisational members, and by the application of a range of tools and techniques for studying health systems. Cycles of improvement are envisaged and measures are identified such that improvements can be monitored (Berwick *et al.*, 1992). The approach has been applied both to administrative and clinical problems, and

the approach is particularly suited to problems where the two overlap. As continuous quality improvement is specifically directed towards systems improvement, there are many examples where its application has implications for risk management. For example, Kibbe *et al.*, (1993) used the approach to address continuity of care issues in a University based family practice, Pachclartz *et al.*, (1992) overhauled a cervical screening service and Rawes (1994) used the approach to engineer "the perfect prescription procedure". Specific skills and a high degree of motivation are required to apply continuous quality improvement methods, but a particular strength is that the approach integrates the investigative features of approaches like significant event auditing, then explicitly identifies and addresses health systems problems which get in the way of desirable outcomes (Shortell *et al*,, 1998).

2.5.2.6 ***Prescribing support.*** Gill *et al.* (1999) conducted a systematic review to identify interventions that affect prescribing behaviour and to derive conclusions for practice and future research. Seventy nine eligible studies utilising randomised trial or pre post intervention designs were identified and there were 96 separate interventions. These were often multifaceted and used audit and feedback, patient mediated approaches, educational materials or educational outreach approaches. Twenty five studies took place in primary care settings, 31 in outpatient settings, 12 in hospital settings and 10 in two settings. About half of the studies demonstrated positive effects and a similar proportion of studies were positive for all approaches. A variety of educational approaches with or without guidelines or educational materials might therefore be expected to improve prescribing practice, providing the combination of interventions is appropriate to the task at hand.

2.5.2.7 ***Pharmacist review.*** Three systematic reviews have examined the activities of clinical pharmacists in outpatient settings (Carter and Helling, 1992; Hatoum and Akhras, 1993; Beney *et al.*, 2000). The most up to date review (Beney *et al.*, 2000) reported positive impacts for patients with hypertension, hypercholesterolaemia, chronic heart failure and diabetes. This research is complemented by two reviews of pharmacists working in hospital settings. The earliest included eight studies evaluating pharmacists' roles in detecting and reporting adverse drug events in the hospital setting (Hatoum *et al.*, 1986) and the second focused on therapeutic drug monitoring by clinical pharmacists (Ried *et al.*, 1989). The first review indicated that more adverse

drug events were detected when clinical pharmacists were involved, but the studies were not designed to assess patient outcomes. The latter review indicated only modest effects on maintaining acceptable drug ranges and only two of the main results achieved statistical significance. Two other studies of clinical pharmacists roles in inpatient settings have been published. Leape *et al.* (1999) conducted a before and after study involving clinical pharmacists in medical and cardiac drug rounds and attributed a 66% decrease in preventable adverse drug events to their involvement. Lipton *et al.*, (1992) conducted a randomised controlled trial in which clinical pharmacists were involved in medications management in a geriatric unit. This study demonstrated clinically and statistically significant decreases in medication errors amongst patients discharged on three or more medications.

2.5.3 Medical Education

The training of competent doctors with good communication skills and the reinforcement of appropriate attitudes and practice during undergraduate medical education will set important precedents which will apply throughout the career of a doctor (GMC, 1993). Many of these attributes are emphasised during vocational training for general practice (Whitehouse *et al.*, 1997) and it is anticipated that new initiatives to promote and support continuing professional development will provide opportunities for busy general practitioners to take time out of practice to address their educational needs, to reflect on their practice and to address quality issues within the organisations they manage (Elwyn, 1998; Conlon, 2003).

2.5.3.1 Undergraduate education. Attitudinal objectives are given much greater emphasis in modern medical school curricula (GMC, 1993) and a move towards teaching these in a general practice setting is a recognition of the importance of these in the primary care setting, and the abilities of general practitioners to teach them (Whitehouse *et al.*, 1990). All doctors need to be able to recognise acute serious illness. For the medical generalist the exclusion of acute serious illness is a key function in any consultation, and diagnostic skills learned at medical school will be brought to bear to assess a range of more or less specific presentations: abdominal pain, headache, chest pain, fever and so on. While these conditions are likely to be included in the core curricula of all medical schools, the clinical epidemiology of these conditions, and the

issue of diagnostic uncertainty should also be represented. Likewise, in the detection of treatable chronic illness, the principles of screening and case finding are important. The integration of public health principles into the teaching of undergraduates will make an important contribution (GMC, 1993).

2.5.3.2 Vocational training for general practice. Communication skills and attitudinal objectives are perhaps given more explicit attention in the training of the medical generalist than in the training of any medical specialist. The consultation is the focus of much of the work in the year spent in general practice and consultation skills include not only communication skills, but also the ability to assimilate information from various sources, note keeping and summarising records, issues around safe prescribing and mechanisms for ensuring appropriate follow up and continuity of care (RCGP, 1972; JCPTGP, 1987). Summative assessment for training in general practice was introduced in September 1996. A year later an act of Parliament was to make satisfactory completion of vocational training a legal requirement for doctors wishing to work as general practitioners in the National Health Service (Peirara Gray, 1997). Professional training in other specialities depends on completion of professional examinations and accredited training posts. Summative assessment for general practice includes not only written papers to assess knowledge and decision making skills, but also videotaped assessments of consultation skills, satisfactory completion of a practice based audit and a trainers' report which covers clinical competence, professionalism, reliability and organisational skills (Campbell and Murray, 1996).

2.5.3.3 Continuing professional development. The old system for the continuing medical education (CME) of general practitioners in the United Kingdom has been swept away with the introduction of professional development plans and annual appraisals. In parallel it has been proposed that practice development plans will be a vehicle by which the educational activities of individual members of health care staff will be explicitly linked to their professional development needs and to the overall development needs of their practices (Elwyn, 1998), an approach that would provide an opportunity to develop multiprofessional working and to link education and quality improvement activities (Field, 1998; Headrick *et al.*, 1998) Primary care trusts are beginning to insist on practices constructing practice professional development plans as a clinical governance activity and it is possible they will be a requirement when

reaccredidation is introduced into general practice (Parboosingh, 1998). As yet there is little experience with the approach in the health sector, but this experience is likely to grow in the future (Pitts *et al.*, 1999).

2.6 CONCLUDING REMARKS

The work of this thesis is directed towards securing a better understanding of general practice as a risk environment for patients seeking and receiving care. Clinical governance in general and risk management in particular should be an important component of care delivery in National Health Service organisations. Adverse events can and do happen in general practice settings and may be underpinned by doctors' characteristics, factors affecting decision making, practice procedures and practice characteristics. In general practice, the emphasis historically has mainly been quality in the consultation, with guidelines and audit (case based and topic based) applied to clinical and to some non clinical issues. Only continuous quality improvement approaches begin to move clinicians away from clinical towards organisation issues and more formal risk assessment approaches such as proactive risk assessments are notable by their absence.

A starting point for this thesis is that there should be more focus on general practice as an organisational form. It is anticipated that understanding the way that accidents occur in general practice settings can bring further insights that will inform improvements in the environment of general practice. In industries outside health care the investigation and analysis of accidents often provides the vehicle for understanding the safety characteristics of organisations and how to improve them. The next chapter features a review of techniques used in the investigation and analysis of critical incidents in healthcare. This review of method compares the detail and performance of different approaches and helps inform the choice of method that is applied in the subsequent research featuring the use of such investigations in general practice settings.

3. REVIEW OF METHODS USED IN THE INVESTIGATION AND ANALYSIS OF CRITICAL INCIDENTS IN HEALTHCARE

3.1 INTRODUCTION

Analyses of accidents and near misses are well established components of risk management in industrial socio-technical systems and complex organisational settings. Detection of trends and elucidation of the causes of accidents are used to inform changes in design or operation that increase safety and reduce the risk of future events. Investigations of major accidents such as the King's Cross Underground fire and the Piper Alpha Oil disaster have acquired a high profile and experience from the airline industry has shown that carefully structured protocols to analyse accidents and near misses can result in timely action to avert disasters in the future (Reason, 1995).

Early indications are that accidents in healthcare share important similarities with those occurring in industrial and organisational settings outside healthcare (Reason, 1993). However, the tradition of developing method for studying accidents and near misses is weaker.

There are some well established frameworks within healthcare, in which the investigation and analysis of critical incidents plays some part. For example analysis of incidents and adverse events feature in confidential enquiries into maternal or postoperative deaths (Walker *et al.*, 1986; Callum *et al.*, 2001), in significant event audit (Pringle *et al.*, 1995), and in some quality assurance approaches that support and extend reporting of incidents (Britt *et al.*, 1997). There are also studies of single and multiple incidents in hospital specialities, in primary care and in psychiatry. Within hospitals, studies have been carried out in intensive care (Wright *et al.*, 1991) anaesthesia (DeAnda and Gaba, 1991; Williamson, 1988) and paediatrics (Waterston, 1988). In primary care there have been studies of prescribing, referrals, deaths, complaints and medical negligence (Berlin *et al.*, 1992; Bradley, 1992a; Hart and

Humphreys, 1987; Owen, 1991) and in mental health, of suicide, attempted suicide and self harm (Meurier, 2000; Redpath *et al.*, 1997; Vincent *et al.*, 2000a). Many healthcare studies refer to an original paper on critical incidents by Flanagan (1954) or to earlier studies using the technique. Some publications provide useful information on the process of enquiry. For instance Berlin and colleagues (1992), describe the actual procedures used in their audit of deaths. It is unusual however for investigators to consider theory, to develop or even describe method, to consider validity or to provide guidelines for others wishing to apply investigative approaches.

Application of investigative methods drawing on the human factors approach in health care settings have yielded new and important insights into patient safety issues (Stanhope *et al.*, 1997; Taylor-Adams *et al.*, 1997; Vincent *et al.*, 2000a). However, it is not clear to what extent such an approach might be considered superior to the performance of other better established methods for investigating incidents in healthcare. Faced with a range of methods and materials of variable quality, this review was conducted for the purpose of establishing the characteristics of the different approaches used. The main approaches were then evaluated against set criteria and assessed for usage in primary care settings.

The review is characterised by a focus on investigative methods, rather than the outcomes of interventions, and draws on materials from different published media and across a range of study designs. The approach was to stay true to the principles of systematic reviews, while drawing on a wider range of materials to appraise individual studies and to assess particular approaches (NHS CRD, 1996: Popay and Rogers, 1998; Giacomini and Cook, 2000). Particular attention is given to the development of an appraisal instrument that supports the extraction of information describing the way that investigations were conducted, an activity that is less often acknowledged as an important step in the conduct of traditional systematic reviews (Laurant *et al.*, 1999).

3.2 METHOD

The objectives of the research were to identify, map and describe the principal methods applied in the investigation and analysis of critical incidents in health care, to discuss the adequacy of the methods and the implications for their application.

The term critical incident is used here as a generic term for an unplanned event or series of events and circumstances that may be associated with undesirable outcomes or near misses. The term critical incident may be used interchangeable with the term clinical incident, to indicate specifically an unplanned event or series of events and circumstances that may result in an adverse clinical outcome (Vincent, 2000).

The identification and review of the relevant literature, involved the following steps:

1. the development of a high sensitivity, high specificity algorithm that can be used to identify relevant citations on electronic databases
2. a search of the Medline database (1981-2001) for relevant materials, using the search algorithm;
3. a screening process to identify descriptive articles and commentaries on the application of investigative techniques and studies featuring the investigation and analysis of incidents in healthcare;
4. a further iteration, reading the literature in order to identify and generate a list of techniques;
5. appraisal of a selection of papers featuring the application of key techniques in health care settings;
6. synthesis of materials on each technique based on descriptive articles and appraised papers;
7. assessment of the techniques against criteria of validity, reliability, acceptability, and utility.

3.2.1 Identification of relevant literature

There are authoritative texts for some (e.g. JCAHO, 2000), but by no means all approaches to the investigation of incidents in healthcare. Furthermore, there has been relatively little reflection on the performance of different approaches under alternative conditions of use. In order to help address these deficiencies a search was made both for descriptive materials and commentaries on techniques and in addition, for published studies featuring the investigation and analysis of incidents in healthcare settings. Appraisals of such published studies then served to expand the knowledge base on the ways in which techniques have been applied in healthcare and provided additional information to support assessments of validity, reliability, acceptability and utility.

3.2.2 Search strategy adopted for the review

The need to access descriptive articles and relevant published studies informed the literature search strategy. This was devised to identify a representative sample of peer reviewed publications featuring the investigation and analysis of clinical incidents in health care and any additional publications, which described or discussed the methods and techniques used. Classic systematic review methodology would require exhaustive searches of electronic databases, supplemented with hand searches, citation searches and communication with colleagues. A modified approach was used in this study, namely an initial systematic search of electronic databases followed by targeted searches of alternative sources for materials providing further detail on the investigative techniques identified. These alternative sources included government documents, web sites and books as well as new papers identified in bibliographies and through personal contacts.

The electronic search strategy was developed to identify relevant papers on Medline 1981-2001, using thesaurus and text terms (see Appendix 1). The search strategy is a modification of the classic search strategy for systematic reviews based on crossing of concepts (Appendix 2). Three concepts were identified, which might appear in publications likely to be of interest for this review:

Concept A Mention of relevant methods of enquiry, investigation or analysis

Concept B Mention of errors, omissions, mistakes or iatrogenesis

Concept C Mention of incidents or adverse events in clinical care

A search directed towards identifying publications featuring all three concepts (Concept A+B+C) was found to be of high specificity, but poor sensitivity. Following experimentation with alternative models a search for publications featuring (Concept A+B) or (Concept B+C) or (Concept A+C) was selected, as this improved sensitivity considerably, albeit generating a fairly large volume of citations for screening.

3.2.3 Inclusion and exclusion criteria

The review was designed to focus on techniques for the investigation of clinical incidents or near misses in healthcare. The aim was to identify two groups of papers: a) studies describing the investigation and analysis of one or more clinical incidents or near misses in a healthcare setting and b) other publications which focus on describing, evaluating and/or discussing method, but without the formal investigation of cases.

There were no country restrictions, but for practical reasons it was only possible to consider publications in the English language. To distinguish from proactive risk assessments a specification was made that investigations should be carried out retrospectively. Completion of forms or interviews documenting details after an incident or near miss occurred was regarded as retrospective, even if this occurred within minutes or hours of the event, but prospective techniques to assess errors such as simulation experiments, or to assess potential errors such as continuous quality improvement or other system redesign approaches were excluded. Epidemiological studies, designed to explore relationships between exposures and patient safety outcomes using statistical methods, were also excluded. Studies designed to assess the reliability of diagnostic tests, which typically featured replication of tests or comparisons with gold standards, were excluded. Finally, autopsy studies were excluded on the grounds that they are designed principally to assess diagnostic accuracy, rather than investigating the causes of error.

3.2.4 Screening of citations and identification of relevant literature

Two investigators examined all titles identified by the electronic search together with their abstracts, then screened hard copies of candidate papers to identify those meeting inclusion criteria.

Citations were classified as i) probable admissible study; ii) probable admissible descriptive paper; iii) possible interest; or iv) no interest. Inter-rater reliability for "probable study or paper" versus "possible or no interest" was monitored using the Kappa statistic, and stabilised at 0.29-0.45. Typically citations were tackled in batches of 100-200 at a time, and then followed by a meeting to resolve any disagreements. This would improve precision given the modest Kappa statistic for the process.

Copies of publications allocated to groups i), ii) and iii) were then obtained. The investigators assessed the content of these materials against a screening checklist. This specified that *either* the paper describes or discusses an investigation method or technique *or* it was a peer reviewed study with all of the following characteristics:

1. The paper featured one or more critical incidents
2. The incident was one in which a patient suffered, or could have suffered harm
3. The incident occurred in a healthcare setting
4. A retrospective enquiry into the incident took place
5. The enquiry included an investigation into error or sub-optimal care

The inter-rater reliabilities for this stage ranged from Kappa 0.19-0.55. Poor descriptions, hybrid designs and inconsistent terminologies were common. This exercise was continued in duplicate, not only to improve precision, but also because the process was considered to be an important preparatory exercise for defining and describing investigative approaches.

3.2.5 Listing and classification of techniques

The papers were examined a second time in order to identify terms in the title, abstract or methods sections that indicated particular approaches or techniques. Candidate terms for the range of techniques were free listed, and organised. It became clear on closer reading of selected papers that many techniques listed were closely related and might be considered as a single "family". Others were represented by no more than one or two examples, and while of interest, did not justify exhaustive consideration in the context of the review. A list of eighteen terms emerged, which was then collapsed into a more manageable classification of six techniques, which would provide the framework for purposive sampling of papers for appraisal and for the synthesis and assessment of techniques in the subsequent part of the review (Figure 3.1). Full descriptions of the essential features of the core techniques were assembled and appear in Appendix 7 (Tables A7:1-6).

Figure 3.1: List of techniques and final classification

First stage classification	Second stage classification[5]
1. Critical incident monitoring	
2. Critical incident technique	
3. Significant event auditing	1. Classificatory reporting [1]
4. Root cause analysis	2. Critical incident technique
5. ALARM/CRU protocol	3. Significant event auditing
6. Confidential inquiry	4. Root cause analysis
7. Occurrence screening	5. Human factors and organisational models
8. Regulatory agency report	6. Comparison with standards approach [2]
9. Claims or complaints analysis	
10. Human factors method	
11. Systems analysis	
12. Active and latent failures approach	
13. Analysis of incident reports	
14. Organisational factors approach	
15. Haddon's matrix	
16. Winnipeg model	
17. Failure modes and effects analysis	
18. Barrier analysis	

[5] The essential features of the six core techniques are summarised in Appendix 7, Tables A7:1-6
[1] Informed principally by literature derived from the Australian Incident Monitoring System
[2] Draws substantially on literature describing the Confidential Inquiry approach in various settings

3.2.6 Development and piloting of the appraisal process

An appraisal form was designed to assist with the systematic documentation of key features of studies investigating critical incidents in health care. This was a substantive exercise as little consideration has been given to the design features of studies investigating clinical incidents in the past, nor to appraising the quality of such studies. The development of the appraisal instrument was informed by the following:

1. Available literature and experience in developing and using appraisal tools in other projects
2. Materials on investigative approaches describing techniques for the investigation of incidents outside healthcare
3. Serial appraisals of studies of investigations within healthcare, with iterative modifications of the instrument over the period of about six months
4. Further modifications of the instrument following preliminary attempts to code, organise and present appraised data

The final version of the appraisal form is included as Appendix 4 and consists of the following sections:

Section A 'Details of the appraised publication' seeks background information about the paper (i.e. country or continent in which the study/report took place, specialty, level of care) and brief outcome information on the critical incident or 'near miss' including the number of events and a summary description.

Section B 'Conduct of the investigation' focuses on 'who' is conducting the investigation, their professional background and investigation experience, and whether the authors refer to an established accident investigation technique and the framework within which investigation took place.

Section C 'Data collection and causal analysis' is divided into three subsections: i) interviews and self reports, ii) primary document review and iii) physical/logistic

assessment. Each section has similar questions on the source of data, methods of data extraction/techniques used, interval between incident and investigation, time taken to extract the information, methods used for data critique and two items on quality assurance regarding data collection and data critique.

Section D 'Presentation and interpretation of data' focuses on how the data is presented in the results and discussion sections. Specifically, questions include how the outcomes of the investigation is formulated, whether these outcomes relate to any underlying model of accident causation, whether recommendations are made and if the level of such recommendations relate to formulation of outcomes and whether there is any intention of implementation of changes as a result of the investigation of the critical incident featured in the paper.

Two investigators participated in the appraisal process. Appraisers undertook to record data evident in the publications and avoided making assumptions. Data abstraction was conducted independently and disagreements in interpretation emerging were resolved by discussion. All papers appraised using earlier versions of the appraisal form were reappraised on items changed during the development process.

3.2.7 Rationale for selection of studies featured in the review

After fifty papers had been appraised, the process was reviewed for the remaining papers eligible for appraisal. The majority of studies identified through the screening process fell within the "classificatory reporting" group or the "comparisons with standards" group and amongst the fifty, the number of papers appraised by technique was roughly proportional to the numbers in the background sample.

Rather than appraising all study papers in the collection, a purposive sampling strategy was adopted at this point, specifying that ten studies would be appraised for each technique, or the total number of papers available, whichever was greater. Maximum variability was sought. For techniques with large numbers of papers available, a range of specialities was targeted across the publication years searched. For techniques with

smaller numbers of publications, further studies were actively sought, through contact with experts in the field. Ultimately the numbers of study papers appraised and presented in this report corresponded to ten each for classificatory reporting, root cause analysis, comparisons with standards; nine for critical incident technique; seven for organisational accident causation models and six for significant event auditing.

3.2.8 Data management and analysis

With the exception of occasional items where it was possible to enter free text, the appraisal instrument took the form of a precoded data abstraction sheet. All data were entered directly using Statistical Package for Social Sciences Version 9 (SPSS Inc, Chicago IL, 1999) and checked back against coding forms. Range and distributions were examined and consistency checks were made across items in the coding array. Anomalies were explored by checking original coding sheets and returning to written publications if necessary and corrections were made to the database where indicated. Key variables were agreed for illustrative analysis of papers representing the six techniques and counts and frequency distributions were generated for the following;

1. Country setting and speciality of appraised papers
2. Source and number of incidents studied
3. The severity of the injuries and the amount of intervention required
4. The characteristics of the individual(s) carrying out the investigation
5. The types of data collection methods used
6. The individuals who were interviewed or who were submitting reports
7. The format of the questionnaire, report or interview
8. The methods used to assure quality when recording and critiquing interviews
9. The methods used to assure quality when collecting data and analysing reports
10. The methods used to assure quality when abstracting and critiquing documents
11. The methods used to assure quality when collecting and analysing data from site visits or physical examinations
12. The level and nature of formulation of the findings on causes
13. The coherence of recommendations and the evidence for implementation

These data were presented for all papers appraised, and stratified by the relevant technique. This presentation was intended primarily to provide an overview of techniques and no formal or statistical comparisons were made.

3.2.9 Comparison of techniques for the investigation in healthcare

A comprehensive account was produced for each technique based on the descriptive publications and the appraised papers. Key information was abstracted to provide the reader with the main features of each technique using a common standard framework, which included:

1. An overview of the technique as typically applied
2. A description of the usual conditions of use
3. A description of the likely formulation and quality of outputs
4. Positive points associated with the technique
5. Negative points associated with the technique

Each technique was then assessed against a predefined set of criteria by two investigators, who agreed jointly the final interpretation. The criteria were adapted from the work of Benner (1985) and Kirwan (1992a, 1992b) and included:

1. Whether the approach is based on an accident model or model of human behaviour which offers theoretical validity
2. Whether the technique assesses or identifies: what happened; how it happened; and why it happened
3. Whether different assessors are likely to utilise the methodology in the same way and expected to be consistent in the conclusions they draw
4. Whether the approach produces balanced and fair outputs – without a focus on the individual only or only the system only.

5. Whether the approach can be expected to be comprehensive in its ability to identify significant errors
6. Whether the approach is likely to be auditable in its documentation
7. Whether the approach is intuitively linked to the generation of error reduction strategies
8. Whether resource use is judged to be to be minimal, modest or substantial
9. Whether the approach has been widely used and acceptable to participants
10. The extent to which the technique is applicable to other specialties

3.2.10 Use in primary care studies

An expanded list of factors that might affect the transferability of each technique were then considered including the following:

1. Whether the approach is proprietary or in the public domain
2. The speciality origins of the technique
3. The specialities where the technique has already been applied
4. The resources that would be required to administer the technique
5. The training and/or experience required to administer the technique
6. The means by which participation is encouraged

Finally, the techniques were assessed against six criteria that indicated the suitability of the approach to the aims and objectives of the research, which included:

1. The validity and consistency of the approach for use in a research setting
2. The sources of data accessed in the course of the investigation
3. The extent to which the approach adopts a broad category based approach or a depth explanatory based approach (or a mix of the two)
4. The extent to which the approach is able elucidate underlying and/or contributory causes of incidents
5. The scope of the recommendations to include observations of relevance to individuals, systems and organisations

6. The range and/or type of incidents that are usually studied.

3.3 RESULTS

The Medline search generated 1961 citations. Six hundred and eighty five papers of possible relevance were identified from titles and abstracts and 562 hard copies were examined (Appendix 5).

Amongst these, 133 publications featured an investigation with analysis of critical incidents (clinical incidents or near misses) in health care settings and a further 106 described or discussed an investigative method or technique. Five additional studies and eight descriptive papers were identified from other sources, principally experts' literature resources or following targeted searches for descriptive materials.

This total literature resource was aligned with six investigative techniques that emerged through the listing and classification process. Overall, this included fifty studies featuring classificatory reporting (CLR) with twenty four descriptive articles, and eleven studies featuring root cause analysis (RCA) with seventeen descriptive articles. There were forty eight studies adopting comparison with standards (CWS) and thirty eight associated articles. Eleven studies featured the critical incident technique (CIT) with four descriptive articles. Twelve studies drew on organisational accident causation models (OACM), with twenty seven descriptive articles, and six featured significant event auditing (SEA) studies with four descriptive articles (Appendix 6).

3.4 APPRAISAL FINDINGS

The final number of study papers appraised and presented in the review correspond to ten each for CLR, RCA and CWS, nine for the CIT, seven for OACM and six for SEA (Figure 3.2).

The following section summarises the data from the appraisal forms giving a comparison of the core techniques. Data are presented section by section as in the appraisal form (see Appendix 4). Figures in parentheses indicate the number of papers for that category, when greater than one.

Figure 3.2: Papers appraised and presented in review

1. Classificatory reporting [1]
   - Morris & Morris, 2000;
   - Steven *et al.*, 1999;
   - Sinclair *et al.*, 1999;
   - Beckmann *et al.*, 1998;
   - Wright & Parker, 1998;
   - Short *et al.*, 1996;
   - Short *et al.*, 1993;
   - Holland *et al.*, 1993;
   - Currie, 1989;
   - Williamson *et al.*, 1985

2. Critical incident technique
   - Cote *et al.*, 2000;
   - Boreham *et al.*, 2000;
   - Meurier *et al.*, 1997;
   - Ely *et al.*, 1995;
   - Orser & Oxon, 1994;
   - Waterston, 1988;
   - Cooper *et al.*, 1984;
   - Cooper *et al.*, 1982;
   - Newbower *et al.*, 1981

3. Significant event auditing
   - Holden *et al.*, 1998;
   - Redpath *et al.*, 1997;
   - Pringle *et al.*, 1995;
   - Bennett & Danczak, 1994;
   - Berlin *et al.*, 1992;
   - Tudor Hart & Humphreys, 1987

4. Root cause analysis
   - Battles & Shea., 2001;
   - Rex *et al.*, 2000;
   - Shinn, 2000;
   - Linden, 2000;
   - Berry & Krizek, 2000;
   - Graber, 1999;
   - Anon, 1998;
   - Haas, 1997;
   - Brown & Fay, 1997;
   - Weinberg & Stason, 1990

5. Organisational accident causation models
   - Carthey *et al.*, 2001;
   - Meurier, 2000;
   - Vincent *et al.*, 2000b;
   - Taylor-Adams *et al.*, 1999;
   - Stanhope *et al.*, 1997;
   - Cullen *et al.*, 1997;
   - Eagle *et al.*, 1992

6. Comparison with standards approach [2]
   - Callum *et al.*, 2001;
   - Cartlidge *et al.*, 1999;
   - Tan *et al.*, 1999;
   - Bucknall *et* al., 1999;
   - Burr *et al.*, 1999;
   - Durrheim *et al.*, 1999;
   - Payne *et al.*, 1993;
   - Walker *et al.*, 1986;
   - Wood *et al.*, 1984;
   - MRWPPM., 1982

[1] Informed principally by literature derived from the Australian Incident Monitoring System
[2] Draws substantially on literature describing the Confidential Inquiry approach in various settings

3.4.1 Section A - 'Details of the appraised publication'

Section A of the appraisal form seeks background information about the paper being appraised.

Table 3.1 gives details of the country or continent in which the study took place and the speciality. All but the CLR approach have been conducted in the United Kingdom and acute care and primary care is featured in most of the techniques. Psychiatry was featured in papers related to CLR approach and the OACM only.

Table 3.1: Details of country setting and speciality of appraised papers grouped by core technique*$

	Country Setting	Speciality	No. of key papers
CLR	• Australasia (8) • Asia (2)	• Family practice • Acute care: Anaesthesiology (6); Intensive care; Obstetric anaesthesia • Psychiatry	10
CIT	• North America (6) • UK (3)	• Family Practice • Acute care: Accident and Emergency; Paediatrics; Anaesthesiology (4); Paediatrics and anaesthetics; Nursing	9
SEA	• UK(6)	• Family Practice (6) •	6
RCA	• North America (9) • UK and North America	• Family Practice • Acute care: Intensive care (2); Transfusion medicine; Anaesthesiology (3); Medical Services; Accident and Emergency and obstetrics; Pharmacy	10
OACM	• UK (5) • North America (2)	• Acute care: Obstetrics (2); Nursing; Intensive care; Anaesthesiology, Cardio-thoracic surgery • Psychiatry	7
CWS	• UK (8) • Africa • Caribbean	• Acute care: Neonatology; Neonatology and obstetrics; Respiratory medicine (2); Infectious diseases; Interventional radiology Obstetrics (2); Obstetrics and paediatrics; • General practice and cardiology	10

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards

$Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

Table 3.2 lists the various sources of critical incidents featured in the publications and the median and range of incidents featured for each technique. Apart from the CLR approach, the different techniques used a variety of sources of critical incidents and all techniques were informed of incidents from voluntary reporting systems.

Table 3.2: Details of the source of critical incidents and median and range of critical incidents featured, grouped by core technique*[$]

	Source of critical incidents	Median and range of critical incidents featured across papers
CLR	• Reporting system (10)	Median = 160 Range = 35-1556 Number of papers = 10
CIT	• Staff recall (5) • Staff recall and reporting systems (2) • Observation, reporting and review • Illustrative case	Median = 96 Range = 1-1089 Number of papers = 9
SEA	• Reporting system (2) • Staff recall and reporting system • Illustrative case • Review • Observation	Median = 168 Range = 1-1263 Number of papers = 6
RCA	• Illustrative case (5) • Reporting system • Reporting system, review, claims and cases brought to attention • Review • Reporting system and review • Not clear	Median = 3 Range = 1-191 Number of papers = 10
OACM	• Staff recall • Illustrative case (4) • Report system and review • Not clear	Median = 1 Range = 1-264 Number of papers = 7
CWS	• Population based surveillance • Reporting systems and review • Reporting system (6) • Staff recall, report and review • Not clear	Median = 166 Range = 42-309 Number of papers = 10

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards

[$]Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

Table 3.3 gives details of the severity of critical incidents featured, including injury

suffered and treatment required. The term 'some injury' included cases where the extent of injury was unknown. The CWS only looked at death as an outcome whereas all other techniques used a variety of outcomes including near misses. A variety of phrases were used in papers to describe outcome including: 'mild, moderate and severe effects', 'minor transient change', 'major physiological change', 'cardiac arrest', 'actual harm', 'life threatening injury', 'foetal distress and low Apgar' and 'clinical deterioration'.

Table 3.3: Details of injury suffered and treatment required for critical incidents featured[*§]

	Severity of critical incidents featured (injury suffered)	Severity of critical incidents featured (treatment required)
CLR	• Death, permanent, temporary and no injury • Death, permanent and no injury • Death, temporary, some and no injury • Death, temporary and no injury (2) • Temporary and no injury (2) • Some and no injury • Not clear (2)	• Major, some and no intervention required (3) • Some and no intervention required (2) • Some intervention required • Not clear (4)
CIT	• Death, permanent, temporary and no injury • Death, permanent and no injury • Death, some and no injury (2) • Temporary, some and no injury • Some and no injury • No injury • Not clear (2)	• Major, some and no intervention required (2) • No intervention required • Not clear (6)
SEA	• Death (5) • Death, permanent, temporary and no injury	• Major, some and no intervention required • Not clear (5)
RCA	• Death (3) • Death, some and no injury (2) • Temporary injury (2) • No injury (2) • Not clear	• Major intervention required (4) • Some intervention required • No intervention required (2) • Not clear (3)
OACM	• Death • Temporary, some and no injury • Temporary injury (3) • Some injury • No injury	• Major intervention required (2) • Some intervention required (4) • Some and no intervention required
CWS	• Death (10)	• Major and some intervention required • Some intervention required • Not clear (8)

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards

§ Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

3.4.2 Section B - 'Conduct of the investigation'

Section B focused on "who" is conducting the investigation, their professional background and investigation experience.

Table 3.4: Details of agency responsible for the investigation, person responsible for the field investigation, their profession and investigation training/experience[*S]

	Person responsible for field investigation	Profession of person responsible	Training/experience in accident investigation
CLR	• Individual reporting the incident (10)	• Medical (4) • Intensive Care Unit staff • Not clear (5)	• Previous experience • Interviewer tried incident form at service • Introduction • Not clear (7)
CIT	• Individuals reporting the incident • Investigator internal to unit (2) • Investigator external to organisation (3) • Investigator (relationship not clear) (2) • Not clear	• Medical (2) • Nursing • Research • Non-anaesthetic investigator • Not clear (4)	• Previous training (2) • Not clear (7)
SEA	• Investigator internal to unit (3) • Investigator external to organisation (2) • Investigators internal to unit & external to organisation.	• Medical (4) • Psychology • Medical, nursing, manager & other non medical staff	• Previous experience • Brief meeting to explain SEA • Not clear (4)
RCA	• Investigator internal to unit (2) • Investigator external to unit (3) • Investigators internal and external to unit • Investigators internal to unit & external to organisation. • Investigator (relation not clear) (2) • Not clear	• Medical (2) • Nursing • Medical, nursing and pharmacy • Nursing and management • Management (2) • Not clear (3)	• Previous training (2) • Previous experience (2) • Not clear (6)
OACM	• Investigators external to org (4) • Investigators external to unit & to organisation • Investigators (relation not clear) (2)	• Nursing (2) • Psychology (4) • Not clear	• Previous experience (2) • Not clear (5)
CWS	• Investigator internal to unit • Investigators internal and external to unit • Investigators internal to unit & external to	• Medical (4) • Medical and nursing (3)	• Previous experience • Not clear (9)

	Person responsible for field investigation	Profession of person responsible	Training/experience in accident investigation
	organisation. • Investigator external to organisation (6) • Investigators (relation not clear)	• Medical and malaria control manager • Medical and non medical staff • Not clear	

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards
$Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

Table 3.4 gives information on the person responsible for the field investigation, and where present details of their profession and investigation training or experience. The CLR approach relied entirely on individuals reporting the incident to provide details concerning the event. CIT studies used both individuals reporting the incident and investigators. The remaining sets of studies used only investigators. Most techniques used investigators that were either internal or external to the unit or external to the organisation or a mixture of these. Studies using an OACM model tended to use only external investigators.

All techniques used individuals with a medical or nursing background as the person responsible for the investigation. Some studies using SEA or RCA have included managerial staff. Thirty eight of fifty two publications did not report whether the person responsible for the field investigation had previous training or experience. Only two techniques (CIT and RCA) included studies that used trained investigators.

3.4.3 Section C - 'Data collection and causal analysis'

This section of the appraisal form is divided into 3 subsections: i) interviews and self reports, ii). primary document review and iii) physical/logistic assessment.

The main method of collecting data for the various techniques is displayed in Table 3.5. 'Not clear' in the columns refers to the number of publications that did not include any information on that particular type of data collection. Three techniques, CIT, RCA and CWS, included one or two publications which conducted physical or logistic

assessment as part of their data collection process. Almost all techniques (except CLR) used primary document review and all techniques used interviewing or self-reporting methods. SEA, RCA and OACM used interview but not self-reporting methods.

Table 3.5: An overview of the types of data collection methods used[*$]

Technique	Interviews and self reports	Primary document review	Physical / Logistic Assessment

CLR	• Yes (10)
	  • 1 interview
	  • 8 self reporting forms
	  • 1 self-report and meeting
		• Not clear (10)	• Not clear (10)

CIT	• Yes (8)
	  • 5 interviews
	  • 2 self-reporting forms
	  • 1 interview + self-reports
	• Not clear (1)
		• Yes (1)
		• Not clear (8)
			• Yes (1)
			• Not clear (8)

SEA	• Yes (4)
	  • 3 group interviews
	  • 1 individual interview
	• Not clear (2)
		• Yes (5)
		• Not clear (1)
			• Not clear (6)

RCA	• Yes (7)
	  • 3 group interviews
	  • 3 individual interview
	  • 1 not clear whether interview or self-reports
	• Not clear (3)
		• Yes (5)
		• Not clear (5)
			• Yes (2)
			• Not clear (8)

OACM	• Yes (7)
	  • 5 individual interviews
	  • 1 group interview
	  • 1 self-reporting form
		• Yes (4)
		• Not clear (3)
			• Not clear (7)

CWS	• Yes (9)
	  • 5 individual interviews
	  • 1 individual interviews + confidential statements
	  • 2 self-reporting forms
	  • 1 individual + group interviews
	• Not clear (1)
		• Yes (8)
		• Not clear (2)
			• Yes (1)
			• Not clear (9)

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards

[$] Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

Tables 3.6 – 3.10 provide comparative information on data collection and analysis,

including only information from papers that used the method of data collection described.

Table 3.6 gives details of the profession of staff involved in providing data relating to the critical incident or near miss. The profession of individuals interviewed or reporting the critical incident was mentioned in 33 of 45 publications that used these methods. However, it was not always clear who was involved in the data collection process. Only the CWS technique collected data from relatives as well as from staff.

Table 3.6: Persons involved in interviews or reports, their recruitment and protection[*S]

	Person(s) interviewed / reporting	Recruitment of informants	Protection of informants
CLR	• Medical staff (4) • Not clear (6)	• Entirely voluntary (10)	• Anonymity assured (9) • Not clear
CIT	• Medical staff • Nursing • Medical and nursing staff (3) • Medical, nursing, pharmacy staff • Not clear (2)	• Voluntary and statutory reporting • Entirely voluntary (6) • Not clear (1)	• Confidentiality and anonymity assured (3) • Confidentiality assured • Not clear (4)
SEA	• Medical and nursing staff • Medical, nursing and health promoter • Admin., medical, nursing manager, trainee and student • Medical, nursing, management, trainee and other	• Entirely voluntary • Not clear (3)	• Confidentiality and anonymity assured • Confidentiality assured (2) • Not clear
RCA	• Medical staff and those directly involved • Medical, nursing, pharmacy staff • Medical, nursing and technical staff, assistant manager & risk management representative • Nursing and other staff • Nursing staff and agency manager • Technical staff, supervisor	• Entirely voluntary • Not clear (6)	• Not clear (7)

	Person(s) interviewed / reporting	Recruitment of informants	Protection of informants
	and other staff • Not clear		
OACM	• Medical and nursing staff (4) • Medical, nursing and pharmacy staff • Nursing staff • Nursing and other staff	• Entirely voluntary (3) • Not clear (4)	• Confidentiality and anonymity assured • Confidentiality assured (4) • Not clear (2)
CWS	• Medical staff (4) • Relative and medical staff • Relative, medical and nursing staff • Not clear (3)	• Entirely voluntary (4) • Not clear (5)	• Confidentiality and anonymity assured (2) • Confidentiality assured (6) • Anonymity assured

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards
$Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

Table 3.7 gives details of the type of method, which additional techniques were used, the mean number of interviewees per case and the duration of each interview. The interval between incident and investigation was not reported in the majority of publications. Exceptions include: one RCA study which conducted their investigation within 7 days of the incident, another RCA study – within 4 days, a third immediately after the incident, an OACM paper - within 48 hours and an CWS publication – within 5 days. Where information was available, the number of interviewees per case varied, with SEA and OACM techniques including up to eight interviewees. Appraised RCA publications did not specify the number of interviewees.

Table 3.7: Type of interview/report, additional techniques used and mean no. interviewees per case*$

	Type of interview / report	Additional techniques used (interviews)	Mean number of interviewees/case	Mean duration of each interview
CLR	• Questionnaire (7) • Questionnaire and open departmental meeting • Not clear (2)	• Assign % contribution to the accident • Not clear (9)	• 1 interviewee • Not clear (9)	• Not clear (10)

	Type of interview / report	Additional techniques used (interviews)	Mean number of interviewees/case	Mean duration of each interview
CIT	• Narrative description • Interview (6) • Questionnaire (1)	• Checklist • Not clear (7)	• 1 interviewee (2) • Not clear (6)	• Not clear (8)
SEA	• Group interview (4) • Individual and group interview	• Preparation of case summary by informant • 8 point framework • Not clear (2)	• 3-8 interviewees • Not clear (3)	• 20-40 mins • 20-60 mins • Not clear (2)
RCA	• Group interview (3) • Individual interview (3) • Not clear	• Conceptual framework • Brainstorming using documentation • Diagrams and flow charts • Fault tree (2) • Not clear (2)	• Not clear (7)	• Not clear (7)
OACM	• Interview (5) • Group interview – to clarify events • Questionnaire	• Checklist (3) • Conceptual framework • Not clear (3)	• 1 interviewee • 4 interviewees • 6 interviewees • 8 interviewees • Not clear (3)	• 20-30 mins (4) • Not clear (3)
CWS	• Questionnaire (3) • Individual interview (2) • Individual and group interview • Narrative description and interview • Questionnaire and interview (2)	• Not clear (8)	• 1 interviewee • Not clear (8)	• Not clear (9)

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards
[$] Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

Table 3.8 gives details of method used for interview or report critique and quality assurance for data collection and critique. Most techniques used established or emergent frameworks, with the exception of CWS methods, which used mostly expert opinion or explicit criteria for assessing data. Two techniques, CIT and OACM, used all three methods, i.e. established frameworks, emergent frameworks and expert opinion. One of three methods of checking the quality of data collection was used in the majority of techniques. Triangulation was used by all except CLR and SEA. CIT, SEA and RCA

used a transcribed record and investigators using CIT and OACM investigation techniques reviewed records. Duplicate assessment with or without inter-rater reliability checks were conducted in CLR, CIT, OACM and CWS methods. Consensus panels were used in CIT, RCA and CWS methods.

Table 3.8: Method used for interview/report critique and quality assurance for data collection and critique*$

	Method used for interview/report critique	Quality assurance - data collection	Quality assurance – data critique
CLR	• Established framework (5) • Emergent framework (2) • Established framework and emergent framework • Computer program • Not clear	• Not clear (10)	• Duplicate assessment • Re-examination of narratives • Not clear (8)
CIT	• Expert opinion • Established framework (2) • Emergent framework (4) • Emergent framework and explicit criteria	• Not clear (4) • Triangulation and record check • Transcribed record (3)	• Duplicate assessment (3) • Consensus panel • Careful checking • Inter-rater reliability • Not clear (2)
SEA	• Emergent framework (4)	• Transcribed record (3) • Decision recorded	• Not clear (4)
RCA	• Established framework (2) • Emergent framework (2) • Established framework and emergent framework • Not clear (2)	• Not clear (3) • Triangulation • Transcribed record	• Not clear (4) • Consensus panel
OACM	• Established framework (3) • Established framework and expert opinion • Expert opinion • Emergent framework • Not clear	• Triangulation and document check (2) • Triangulation • Documentation checked • Not clear (3)	• Discussion with clinicians • Inter-rater reliability • Not clear (5)
CWS	• Expert opinion (6) • Explicit criteria (2) • Not clear	• Triangulation (3) • Not clear (6)	• Consensus panel (4) • Duplicative assessment (2) • Not clear (3)

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards
$Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

Table 3.9 shows the source of document data, and where available, methods of data

extraction. Sources of document data include medical and prescribing records, protocols, post-mortem reports, death certificates, coroner's court reports, public and mortuary reports. Investigators using RCA and CWS methods tended to use a variety of primary documentation. For thirteen of twenty three of the papers it was not clear how the data was extracted. Other publications indicated whether narrative summaries (SEA, RCA, CWS), abstraction forms (SEA, CWS) or questionnaires (CWS) were used.

Table 3.9: Source of document data and methods for data extraction[*§]

	Source of document data	Methods used for data extraction
CLR	This method was not used in any papers appraised for this technique	
CIT	• Medical record •	• Not clear
SEA	• Medical record (4) • Medical record and PM report	• Data abstraction form (2) • Not clear (2) • Narrative summary
RCA	• Medical record (2) • Protocol(s) • Medical record and protocols • Medical and prescribing record and protocols	• Narrative summary • Not clear (4)
OACM	• Medical record (3) • Not clear	• Not clear (4)
CWS	• Medical record (3) • Medical record and PM report (2) • Medical record, prescribing record and death certificate • Medical record and death certificate • Police, coroner's court reports, public and mortuary reports	• Data abstraction form (4) • Questionnaire • Narrative summary and questionnaire • Not clear (2)

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards
§ Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

Table 3.10 gives details of methods used for document critique and quality assurance for data collection and critique. Only key publications describing the OACM method used an established framework to analyse data from primary sources. Papers grouped under SEA and RCA techniques used emergent frameworks for document critique, whereas RCA, OACM and CWS techniques made use of expert opinions. There is little information on quality assurance for this type of data collection, with RCA and CWS models using duplicate abstraction and OACM using triangulation. In contrast

appraised publications have provided information on the different types of reliability checks for data analysis, using consensus panels (all except CLR and OACM), inter-rater reliability (OACM, CWS), duplicate abstraction (CWS) or a combination of two or three of these methods (CIT, SEA, CWS).

Table 3.10: Method used for document critique and quality assurance for data collection and critique*$

	Methods used for document critique	Quality assurance – data collection	Quality assurance – data critique
CLR	This method was not used in any papers appraised for this technique		
CIT	• Not clear	• Not clear (3)	• Not clear
SEA	• Emergent framework (2) • Not clear (3)	• Not clear (5)	• Consensus panel • Review by second researcher • Not clear (3)
RCA	• Emergent framework • Expert opinion • Not clear (3)	• Duplicate abstraction • Not clear (4)	• Consensus panel (2) • Not clear (3)
OACM	• Established framework and expert opinion • Chronology of events • Not clear (2)	• Triangulation • Not clear (3)	• Inter-rater reliability • Not clear (3)
CWS	• Expert opinion (5) • Explicit criteria (2) • Explicit criteria and expert opinion	• Duplicate abstraction • Not clear (7)	• Duplicate abstraction • Consensus panel (4) • Inter-rater reliability • Not clear (2)

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards
$Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

Only publications which collected and analysed physical or logistic data (one using CIT, two using RCA and one using CWS methods) are presented in Table 3.11. Information on this type of data was particularly sparse with no information on the time taken for assessment and quality assurance both for the collection and analysis of data. Only one RCA paper had information on checking the reliability of analyses, a case where a drug sample was sent to two laboratories.

Table 3.11: Source of physical/logistic data, observational techniques used, interval between incident and investigation and methods for judging this type of data[*$]

	Source of physical / logistic data	Observation al techniques used to gather data	Interval between incident and investigation	Methods used for judging physical / logistic aspects
CIT	• Site visit	• Inspection	• Immediately after the event	• Not clear
RCA	• Site visit (2)	• Chemical analysis (2)	• 'Within days' • Not clear	• Expert opinion (2)
CWS	• Site visit	• Not clear	• 5 days	Not clear

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards
$Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

3.4.4 Section D - 'Presentation and interpretation of data'

Section D focuses on outcomes of investigated cases.

Table 3.12 presents information on the formulation of outcomes and the use of underlying models to explain accident causation. All techniques included papers that either i) focussed on clinical or patho-physiological issues, ii) included a classification of different types of errors or iii) contained the elucidation of causes of errors or a combination of two or three of these.

All studies using the OACM technique analysed the causes or contributing factors associated with the critical incident. In thirty five out of fifty two papers it was not clear if the outcome was related to any underlying model of accident causation. Key papers appraised for the SEA technique did not include any references to associated theories.

Table 3.12: Formulation of outcomes of accident investigation and model of accident causation[*$]

	How are the outcomes of the critical incident investigation(s) formulated	Do the outcomes relate to any model of accident causation?
CLR	• Focus on clinical and patho-physiological issues • Classification of different types of errors • Clinical and patho-physiological issues & classification of errors • Elucidation of causes of errors (3) • Classification & causes of error • Clinical and patho-physiological issues & classification & causes of errors (3)	• Allnut model (2) • Active and latent failures • Not clear (7)
CIT	• Focus on clinical and patho-physiological issues • Elucidation of causes of errors (2) • Classification & causes of error (2) • Clinical and patho-physiological issues & causes or errors • Clinical and patho-physiological issues & classification & causes of errors (3)	• Active and latent failures • Active and latent failures + contributing factors • Not clear (7)
SEA	• Clinical and patho-physiological issues & classification of errors (2) • Clinical and patho-physiological issues & contributory factors (e.g. communication) • Classification of different types of errors (2) • Clinical and patho-physiological issues, classification of errors & factors related to patients, GP practice, or hospitals	• Not clear (6)
RCA	• Classification of different types of errors • Elucidation of causes of errors (5) • Clinical and patho-physiological issues & causes of errors • Classification & causes of error (2) • Not clear	• Active and latent failures • Decision making & Eindhoven Classification Model • Not clear (8)
OACM	• Elucidation of causes of errors (3) • Classification & causes of error (3) Clinical and patho-physiological issues, classification of errors & illustration of contributory factors	• Active and latent failures (4) • Contributory factors • Active and latent failures + contributory factors (2)
CWS	• Focus on clinical and patho-physiological issues (2) • Classification of different types of errors • Clinical and patho-physiological issues & classification of errors (4) • Clinical and patho-physiological issues & identification of factors (i.e. disease, patient and doctor factors) • Clinical and patho-physiological issues & classification & causes of errors (2)	• Active and latent failures • Contributory factors • QA/audit • Not clear (7)

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards

$Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

The remaining papers included at least one publication that referred to Reason's active failures and latent conditions. In addition, two CLR publications referred to Allnutt's (1987) 'human factors in accidents'; a CIT publication, two OACM publications and one comparison with standards publication included Vincent et al's (1998) contributory factors model; and an RCA paper refers to Rasmussen's (1976) decision making model and Van der Schaaf's (1992) Eindhoven Classification Model.

Table 3.13 identifies whether papers make recommendations, which might lead to improvements in patient safety and whether they provide an account of the implementation of changes. In twenty four of fifty two papers, patient safety recommendations were made based on the errors identified in investigations, or their underlying causes. In SEA and CWS recommendations were based on errors, but none from elucidation of causes, and in OACM, recommendations were based on causes, but none on errors. In CLR, CIT, SEA and CWS, general recommendations for improving patient safety were made, without clear links to errors and/or their causes in the investigative part of the study. In RCA and OACM, either no recommendations were made, or those that were made followed on from errors and/or causes identified.

Table 3.13: Recommendations and implementation of changes[*S]

	Are recommendations made which might lead to improved patient safety?	Implementation of changes?
CLR	• Discussion of methods/approach used • Discussion of methods/ approach used and the size of problem • General suggestions for improvement • Discussion of size / scope problems and general suggestion for improvements (2) • Discussion of size/scope problems and solutions based on *causes* • Discussion of methods/ approach used, the size of the problem and solutions based on *causes* identified • Discussion of size problem, general suggestions improvements & solutions based on *errors*	• No discussion of implementation (6) • Description of implementation of changes (2) • Implementation and informal evaluation • Implementation and formal evaluation

	Are recommendations made which might lead to improved patient safety?	Implementation of changes?
	identified • Discussion of methods used, size of problems and general suggestions for improvements • Discussion of method / size of problem and solutions based on *errors* & *causes* identified	
CIT	• General suggestions for improvement • Specific solutions based on *causes* identified (2) • Discussion of methods and general suggestion for improvements • Discussion of methods and solutions based on *causes* identified • Discussion of methods and solutions based on *errors* identified • Discussion of methods/ size of problem and specific solutions based on *causes* identified • Discussion of methods / size problem, general suggestions for improvement & specific solutions based *error* identified • Discussion of methods and specific solutions based on *errors* and *causes* identified	• No discussion of implementation (8) • Individual reports of implementation of changes in individual practice
SEA	• Discussion of methods and size of problem (2) • Discussion of methods used, size/scope of the problem, and general suggestions for improvements • Discussion of methods and general suggestions for improvements • Discussion of methods and specific solutions based on *errors* identified (2)	• No discussion of implementation (2) • Statement of intention for implementation • Description of implementation of changes (2) • Implementation and formal evaluation
RCA	• Discussion of methods/approach used (2) • Specific solutions based on *errors* identified (4) • Specific solutions based on *causes* identified (3) • Discussion of method / size of problem and solutions based on *errors* & *causes* identified	• No discussion of implementation (4) • Description of implementation of changes (4) • Implementation and *in*formal evaluation • Implementation and formal and *in*formal evaluation
OACM	• discussion of methods/approach used (3) • discussion of methods and size of problem • discussion of methods and specific solutions based on *causes* (2) • Discussion of methods/ size of problem and solutions based on *causes* identified	• No discussion of implementation (6) • Statement of intention for implementation
CWS	• General suggestions for improvement (3) • Specific solutions based on *errors* identified (3) • Discussion of methods/approach used and	• No discussion of implementation (7) • Statement of intention for implementation (2)

	Are recommendations made which might lead to improved patient safety?	Implementation of changes?
	size/scope of the problem (2) • Discussion of methods and solutions based on *errors* identified • Discussion of methods/approach used, the size/scope of the problem, general suggestions for improvement & solutions based *causes* identified	• Description of implementation of changes

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards
$Not clear: "Not clear" is used in the table when relevant information could not be located in the text of the paper

No tradition of discussing and evaluating changes made as a result of investigations appeared in relation to any particular technique. Changes made as a result of findings were discussed in fifteen papers and discussion included mention of formal or informal evaluation of changes made in six papers.

3.5 EVALUATION OF INCIDENT INVESTIGATION TECHNIQUES

Information was assembled from descriptive papers and from the appraised papers for each of the six core techniques. Descriptions of the essential features of the core techniques appear in Appendix 7 (Tables A7:1-6).

The techniques were then assessed against predefined criteria and the features were compared and contrasted.

3.5.1 Assessment of techniques against set criteria

The findings of the formal assessment of techniques against criteria of validity, consistency, likely independence and comprehensiveness, whether auditable, likely impact, resource usage, acceptability and applicability appear in Table 3.14.

Table 3.14: Assessment of health incident investigation and analysis techniques*

Technique	ASSESSMENT CRITERIA
	Theoretically Valid - (i) Model-based
CLR	Moderate, some studies make reference to a model
CIT	Low, one or two studies make reference to Reason's active and latent failures
SEA	Low, a loosely defined framework is included
RCA	Low to moderate model based theoretical validity
OACM	High theoretical validity, model used in all analyses
CWS	Low – little reference to theoretical models
	Theoretically Valid - (ii) What /how / why
AIMS	Moderate – difficult to assess, some studies refer to all three questions, others just consider what happened or how it happened.
CIT	Sophisticated in Cooper's original paper. Little developed since Low – moderate, some studies focus on one or two of the questions: what and how, but no classification system.
SEA	Difficult to assess - a framework is presented which *may* include exploration of these three questions Low – moderate, some studies focus on one or two of the questions: "what" and "how", but little information on underlying causes
RCA	Difficult to assess because of contrast of theory and evidence in papers. Depends on the skill of the assessor. Technique has capacity to answer all three questions
OACM	Moderate, focus on "why" question with some "how" questions answered
CWS	Moderate, focus on "what", with some "how" and occasionally "why"
	Consistency (Accuracy)
CLR	Moderate – high consistency
CIT	Low (not well specified enough)
SEA	Low (not well specified enough)
RCA	Low – moderate, a mixture of established and emergent framework and not clear responses from appraised papers
OACM	Moderate – high
CWS	Low – moderate, mainly based on expert opinion
	Independence
CLR	Low – moderate, few studies reported balanced and fair outputs. Dependent on local involvement and investigator focus
CIT	Low – moderate, as relies on local knowledge, local involvement
SEA	Low – moderate
RCA	Moderate – high, conflicting evidence
OACM	Moderate – high, theories consider wide range of factors
CWS	Low, few papers use theoretical models to analyse data
	Comprehensiveness
CLR	Difficult to judge – some of the three criteria of comprehension in some publications
CIT	Yes, potentially so, if expert investigators

Technique	ASSESSMENT CRITERIA
SEA	Low-moderate
RCA	Moderate – high, depends mainly on the skill of the assessor
OACM	High, when used correctly
CWS	Low – moderate, some focus on errors, but breath of coverage and ability to identify all possible error is not clear
	Auditable Documentation
CLR	This is difficult to assess as there is conflicting evidence. The summary and knowledge of this technique suggests high documentation, but appraised papers indicate moderate documentation
CIT	Moderate
SEA	Moderate
RCA	Moderate – high, again conflicting evidence
OACM	Moderate – high, use of checklist for staff and forms for investigator
CWS	Moderate – high, use of data abstraction forms and questionnaires
	Error Reduction
CLR	Moderate – some generation of error reduction mechanisms
CIT	Potential for error reduction to follow; partially realised in practice; Moderate – high, general or specific solutions made in all papers appraised
SEA	Moderate – high
RCA	Moderate or possibly high generation of error reduction mechanisms
OACM	Low – moderate, focus on method with some solutions offered
CWS	Moderate – high, mostly generates error reduction mechanisms, but some publications focus on approach and size/scope of problem.
	Resources (Usage)
AIMS	Low – moderate, completion of forms mainly
CIT	Low – moderate, depending on the type of incident
SEA	Moderate
RCA	Moderate – this depends on the severity of the case under investigation
OACM	Moderate, mainly use interviews and re-interview if necessary
CWS	High, use of record review and interviews of staff and sometimes relatives
	Acceptability (Usage)
CLR	High – an established system of incident monitoring
CIT	Good/high, has been widely used for some time as until recently there was little alternative
SEA	High – particularly in primary care and mental health
RCA	Moderate, but beginning to be more widely used and accepted
OACM	Moderate, starting to be used by National Patient Safety Agency as well as for some local investigations
CWS	Possibly wide use of audit and peer review methods, but confidential enquires are led by few specialist groups
	Applicability (Usage)
CLR	High
CIT	Wide range of specialities
SEA	Moderate, some focus on deaths
RCA	High applicability

Technique	ASSESSMENT CRITERIA
OACM	High, can be used for any incident within healthcare
CWS	Wide range of specialities, but the focus of confidential enquires is on deaths

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA –Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards

CLR and OACM were judged to have higher levels of model based validity on account of theoretical underpinnings. All techniques scored low or moderate in the degree to which they addressed "what", "how" and "why" questions. Different techniques tended to have different emphases. CLR for example is applied in a system that detects and collates incidents, so tends to focus on "what" and "how" questions, while OACM, was typically used to study single incidents, and drills down to understand the complexities of "why".

Most techniques were judged as low or low-moderate consistency except CLR and OACM, which was though likely to have higher consistency on account of their inherent structures. Individual assessments within CWS were expected to have low consistency, hence the use of replicate assessment or panels in confidential enquiries.

Independence varied, with RCA and OACM considered the best, as they adopt a more open approach to investigation, incorporating a wide range of influences and outcomes. OACM scored high on comprehensiveness. RCA and CIT also could provide comprehensive investigations. For these three techniques, the skill of the investigators would be an influence on the degree to which investigations would be comprehensive.

All techniques had moderate to high auditable documentation, but this may vary according to conditions of use. It was acknowledged that CIT used in a research setting for example, might include transcription of interviews and formal analysis of the content of those interviews. Error reduction, an important objective in incident investigation and analysis was mostly moderate-high. OACM was classified as low as the papers describe mainly method. A protocol (Vincent *et al.*, 1999) argues that the investigation report from OACM easily translates into improvement plans, but no examples were published at the time of the review.

The resource use in conducting individual investigations varied and this may depend on the type of incident, or may reflect discrepancies between the theory of a technique and its practical application. SEA, RCA and OACM were more resource intensive that say completing a monitoring form and at the time of writing RCA and OACM were not widely used in healthcare in the United Kingdom, although all techniques are in the public domain. Lower levels of acceptability might in part be due to the more recent history of RCA and OACM in healthcare in the United Kingdom and to lower levels of dissemination of the methods.

Applicability was considered broadest for CLR, RCA and OACM. Different techniques have often been developed in particular speciality areas (e.g. CLR and CIT in anaesthetics, SEA in general practice) but for all techniques there was evidence for transferability across specialities. In principle, techniques may be applied to serious adverse incidents or near misses. In practice more serious incidents were over represented in RCA, OACM and CWS in the context of confidential enquiries.

3.5.2 Transferability and suitability for use in primary care settings

Table 3.15 summarises characteristics of investigative techniques that will be relevant to their transferability to primary care settings.

The details of techniques are similar in terms of public availability, and most have been used across a range of specialities. There was variation in the level of expertise and training required across techniques and also in the extent to which techniques encourage participation in investigations, each of which will affect the usability of techniques. The range of techniques in the RCA "toolbox" implied more extensive training than OACM and some appeared overly detailed for use in primary care settings. Both techniques are time intensive, but OACM is less so for informants, as individual interviews are more usual. This might also increase the likelihood of participation given disclosure in group settings can be more problematic.

Table 3.15: Factors affecting transferability to primary care setting*

Technique	Domain	Speciality origins	Speciality applications	Resource use	Training requirements	Participation
CLR	Public	Anaesthetics	Various, including primary care	Mod-high depending on scope: computer programme to analyse data	Medium, some training given to staff for reporting incidents, but little information on training for analysis	Voluntary involvement
CIT	Public	Anaesthetics	Various, including primary care	Low-mod depending on scope: specific expertise needed to assemble and analyse data	Little training for technique per se (as limited) but considerable speciality expertise needed	Voluntary involvement
SEA	Public	General practice	Also used been used in mental health.	Low-moderate	Facilitation skills	Voluntary or governance
RCA	Public	Mixed	Mainly secondary care	Low-moderate: but high on a per case basis	Medium/high level of training required depending on level of expertise required	Voluntary or governance
OACM	Public	Obstetrics	Mainly secondary care. Has been used in mental health	Low-moderate: but high on a per case basis	Medium level of training necessary	Voluntary or governance
CWS	Public	Obstetrics	Mainly secondary care.	High; typically a major activity across many institutions	Little training for technique per se (as limited) but considerable speciality expertise needed	Voluntary or governance

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA – Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards

Assessment against criteria indicating suitability for use in the primary care studies appears in Table 3.16.

Two of the six techniques, RCA and OACM, appeared methodologically robust and offered depth approaches to investigate system issues. They could be used to investigate serious incidents or near misses. For both, the emphasis was on depth investigation and the identification and/or monitoring of incidents did not fall within the remit of the methods. However, there are examples of such methods being nested within other approaches that take a more quantitative approach. For example RCA has been used to address selected events featuring in reporting systems (Rex *et al.*, 2000) and OACM within an occurrence screening framework (Neal *et al.*, 2001).

Table 3.16: Suitability for use in primary care studies*

Technique	Validity-consistency	Data sources	Breadth versus depth	Formulation	Recommendations	Range of incidents
CLR	Moderate	Reporting form	Breadth	Errors, causes	Individuals, systems	Minor-serious
CIT	Low-moderate	Reporting form or interviews	Depth	Errors, causes	Individuals, systems	Minor-serious
SEA	Low-moderate	Group interview and records	Depth variable	Errors, causes	Individuals, systems	Minor-moderate
RCA	Moderate	Group interview and records	Depth	Causes	Systems	Moderate-serious
OACM	Moderate	Interviews and records	Depth	Causes	Systems, organisations	Moderate-serious
CWS	Low-moderate	Questionnaire, records, interviews	Breadth and depth	Errors	Individuals, organisations	Serious

*Core techniques: CLR -Classificatory reporting; CIT -Critical incident technique; SEA –Significant event audit; RCA – Root cause analysis; OACM –Organisational accident causation model; CWS – Comparison with standards

3.6 DISCUSSION

3.6.1 Summary of findings

A substantive literature was reviewed featuring investigations into clinical incidents in healthcare settings. A list of techniques was developed which was collapsed into six categories: classificatory reporting systems (CLR); critical incident technique (CIT); significant event audit (SEA); root cause analysis (RCA); organisational accident causation models (OACM) and comparison with standards (CWS). Approaches exhibited a range of performance characteristics when formally assessed against criteria of adequacy. The finer detail of how the methods were applied in practice emerged through appraisal of published studies.

Although a formal ranking of techniques is neither useful nor valid, there were some significant differences between techniques on specific criteria. Most techniques for instance were rated as having a low or low-moderate consistency except OACM, which had high consistency. Error reduction an important objective in incident investigation and analysis, was mostly moderate-high except in OACM where it as low (as the focus was on the investigation method). RCA and OACM considered the widest range of contributory factors and CLR had the greatest attention to fine clinical detail. Acceptability or usage of techniques varied and was difficult to assess. This may reflect the fact that many techniques are relatively new and because there is generally little information on the extent of their usage.

Techniques were considered against criteria for transferability and other criteria of suitability for the purpose of investigating incidents in primary care. Resource use was high for CLR and CWS approaches and requirements for training were high in RCA and OACM. RCA and OACM offered depth approaches. OACM was more theoretically robust and required less training than RCA.

3.6.2 Methodological issues

No previous attempt has been made to review and synthesis the literature on the analysis of critical incidents and adverse events in health care. Descriptions of approaches taken in healthcare were, for the most part embedded in particular studies. The appraisal tool created to support this study remains an important resource for conceptualising and evaluating methods for the investigation of incidents in healthcare.

There were a larger number of potentially relevant studies for review than originally expected. Although the review meets the objectives of mapping, describing and evaluating different approaches, the sampling strategy does not assure representativeness of publications within investigative classifications. As such, caution is required when considering issues such as the extent to which an approach has been used in a particular speciality, or the volume of publications on particular methods from particular countries, or during particular time periods.

This research describes the major techniques for investigating incidents, but is not exhaustive. For example, single publications were identified describing Haddons matrix as an approach to addressing patient safety (Brasel *et al.*, 2000) and another on failure analysis (Feldman and Roblin, 1997). Of relevance to the research that follows is the observation that a small number of occurrence screening studies were identified by the literature search (Leape *et al.*, 1991; Wilson *et al.*, 1995; Neale *et al.*, 2001). While this design appeared to be a useful approach for capturing incidents, in most publications, there was little detail on method applied to investigating incidents, so the material was not included in the sample.

The approach used to assess the adequacy of the techniques still requires independent validation. This has been used previously to assess methods outside healthcare (Woloshynowych *et al.*, 2005), but the information available for the assessment of methods within healthcare was qualitatively and quantitatively different. The approach appeared to have face validity and there was reasonable consistency between individuals involved in assessments, but more formal validation of the approach would be useful.

3.6.3 Implications for investigations in primary care

This research did not support any judgement of "best" methods for the investigation and analysis of critical incidents in healthcare. Different approaches were more or less suitable for different contexts and purposes. Some, but not all techniques were embedded in frameworks that enabled the identification of clinical incidents, notably CLR as exemplified by the Australian Incident Monitoring System and CWS as in the Confidential Inquiries. The remaining four techniques, CIT, RCA, SEA and OACM are all primarily aimed at local investigation and analysis. They cannot produce generalisable results, and can say nothing about the scale of a problem, but they can provide substantive qualitative learning from smaller numbers of incidents.

The broad aim of this thesis is to explore the structural characteristics of general

practice that have implications for patient safety. The aim demands a qualitative rather than a quantitative approach to the research and the intention to link the work with modern theories of accident causation predicates the use of an investigative technique that is itself theoretically grounded. The approach developed by Vincent *et al.* (1999) appeared fit for purpose. There remained a tension however, between the requirement of conducting a series of coherent, meaningful depth investigations, and the method adopted for identifying critical incidents, which was addressed by a nested study design as described in Chapters 5 and 6.

The depth investigative approach had not previously been used in primary care settings. It was one of the methods for which a protocol was available, but the degree to which the approach could be transferred from hospital or mental health care settings to primary care needed to be explored and the next chapter describes piloting and adaptation of the approach.

4. DEVELOPING AND TESTING A METHOD FOR INCIDENT INVESTIGATION AND ANALYSIS IN PRIMARY CARE

4.1 INTRODUCTION

In the previous chapter, the strengths and limitations of techniques applied to the investigation of incidents in healthcare were compared and contrasted. It was argued that there is no "best" approach, as methods have been developed for use in different contexts and settings. Root cause analysis (RCA) and organisational accident causation models (OACM) scored highly against a majority of evaluation criteria and both methods are suitable for investigating single or small numbers of events. RCA probably requires more experience in the use of a wider range of techniques for successful application and investigations drawing on organisational accident causation (OACM) models were thought to be the most suitable for addressing the aims and objectives of this thesis.

This chapter describes developmental work in primary care settings with an accident investigation protocol constructed around a robust organisational accident causation model, grounded in the human factors approach (Stanhope *et al.*, 1997, Vincent *et al.*, 1998). The "human factors approach" is a hybrid discipline, which focuses on the influences on human players within complex organisational systems. A feature of the investigative method applied in its most developed form is the identification of acts or omissions that might have contributed to an incident, followed by an explicit enquiry into systemic features operating at different levels that could have influenced the actions taken.

A protocol was available for application of the investigative technique in hospital settings (Vincent *et al.*, 1999). The protocol had originally been developed for use in obstetrics (Stanhope *et al.*, 1997). It was subsequently tested in other medical

specialities and in mental health (Taylor-Adams *et al.*, 1997; Vincent *et al.*, 2000a) but there was no work with the approach in primary care.

General practitioners are independent contractors, who run small businesses employing administrative and nursing staff and providing the first point of contact with the health system for the majority of people with health concerns. They function as part of an extended primary care team that also includes professionals such as community nurses and health visitors, who are employees of other NHS organisations. An investigative framework developed for use in secondary care settings cannot therefore be assumed to be applicable and acceptable in primary care. Also the conduct of investigations may be more challenging in primary care settings. General practitioner informants may feel under fewer obligations to participate in investigations than hospital colleagues, episodes of care may be longer than is usual in hospital settings and the patient journey may be more complex. Medical records in general practice can lack detail and different staff involved with the care of patients in their own homes might work from different sites.

The chapter describes a series of activities directed towards assessing the face validity, acceptability and d feasibility of conducting investigations in primary care settings. The learning from these activities was incorporated in sequential modifications of the original protocol, to generate guidance adapted for use in primary care that would underpin the methodology of the investigations featuring in the original research described later. No pre-pilot work was conducted of the occurrence screening approach used to ascertain cases for those investigations as this is already a well established design in patient safety research (Bennett and Walshe, 1990).

4.2 METHOD

The investigation methodology that is the subject of the research in this chapter is described in detail elsewhere (Vincent *et al.*, 1999). The methodology draws on Reason's Organisational Accident Model, originally developed for use in complex

industrial systems as a means of understanding the relationships between the various factors involved in the genesis of accidents, and to identify methods of accident prevention (Reason, 1995).

It is argued that to understand and prevent adverse events in medicine, it is necessary to make a distinction between the actions of individuals and characteristics of the work environment as the latter can have a significant bearing on the likelihood that accidents will occur. The investigative method provides a framework of contributory factors, primarily derived form medical publications on error, adverse outcomes and risk management (Vincent and Taylor-Adams, 2001). In early studies these were presented in checklist format during interviews with staff involved in incidents (Stanhope *et al.*, 1997). In later applications, the factors have been incorporated in a more fluid way into the enquiry and used subsequently to help structure a systematic report, which should in turn, inform recommendations for change (Vincent and Taylor-Adams, 2001).

Figure 4.1 Summary of the investigation process

1. Agree that a clinical incident has occurred and establish that staff are willing and able to enter into an open and frank discussion
2. Establish a summary of the circumstances as they appear from a member of staff close to the case and decide which process of care requires investigation
3. Establish a chronology of events by interviewing staff and with access to documentary or other records
4. Revisit the sequence of events and ask questions about any problems that appear to have occurred
5. Ask questions about the reasons for any problems exploring patient, staff, task, team, work environment, organisational management and policy related factors
6. Write up the interviews and assemble a composite analysis under each of the problems identified
7. Compile a report on the event, listing the causes of problems arising and make recommendations for improvements

From Vincent and Taylor-Adams, 2001

4.2.1 Investigation methodology

A summary of the investigative process appears in Figure 4.1. The approach is interview based, building on information available from medical records and other documents.

There are several distinct phases to the interview. The first step is to examine role of the informant and to establish their account of the chain of events that led to the accident or adverse outcome. In the second step, the interviewer introduces the concept of the care management problem. The task is to identify all important acts or omissions by staff that might have had a bearing on the outcome. Each of these is comprises a "care management problem". Then, the investigator looks further back at the conditions in which staff were working and the organisational context in which the incident occurred, doing so for every care management problem identified. Questions address contributory factors at different levels, drawing on headings in a framework that include patient factors, individual staff factors, task factors, team factors, organisation and management factors and policy issues (Figure 4.2).

Figure 4.2 Framework of factors informing structured interview

- Patient factors: complexity and seriousness of condition, language and communication, personality and social issues
- Individual staff factors: Knowledge and skills, competence, performance issues, behaviour and attitude
- Task factors: Task design, availability and use of protocols, systems and information support
- Team factors: Verbal and written communication, support and supervision, team structure and function
- Work environment: Staffing levels and skill mix, workload and rota or shift systems, technical, managerial and administrative support
- Organisational and management: Financial resources and constraints, organisational structure and function, policy standards and goals
- Institutional context: Economic and regulatory context, national standards and performance targets, governance and professional regulation

From Vincent and Taylor-Adams, 2001

There is a standard format for writing up reports that includes text and summary chronology, followed by each care management problem and associated contributory factors. The list of contributory factors provides the pointers to areas that might be included in an action plan (Vincent and Taylor-Adams, 2001).

4.2.2 Evaluation research

Participatory research and evaluation methods were used (Cornwall and Jewkes, 1995) to assess the validity, acceptability and feasibility of using the investigative methodology in primary care, drawing on the experience of stakeholders to whom the investigative approach and associated outcomes would have greatest relevance. The stakeholders identified were general practitioners and other staff working in primary care, service managers with responsibility for quality and safety in this setting and academics interested in research in general practice.

The key objectives of the evaluation research were:

- to establish the face validity of the investigative approach, amongst primary care staff,
- to establish the acceptability of the method as an approach for use by service and research staff.
- to establish the feasibility of conducting depth investigations using the method in primary care settings
- to produce guidance tailored for use in primary care settings

The evaluation research encompassed a range of interrelated activities some of which were conducted in parallel and all of which contributed to the development of guidance for use of the investigative approach in primary care settings. Use of multiple methods enabled an element of triangulation of data collection through participant observation, direct application of investigative methods, reflective and iterative discussion and use of documentary evidence (Denzin and Lincoln, 1994).

The specific activities included:

1. A presentation of the investigative approach to a large, mixed audience of staff working in primary care, who might conceivably be involved in investigations of incidents

2. Application of the method to case vignettes with health services staff and academic staff who might use the investigative approach in service or research settings
3. Real time investigation of cases identified by the investigator and general practitioner colleagues with and without academic links, with reflexive evaluation of process and outcome
4. Development of investigative guidance with iteration of drafts through a consultation group comprising a group of staff who worked in local primary care organisations

A chart illustrating the research design appears in Appendix 8. Further detail of the different elements of the research is now presented.

4.2.3 Group meeting involving general practice staff

The investigator, the originator of the investigative method, representatives from the National Patient Safety Agency and from a medical insurance agency, were guests at a locality event in which all general practices within a single Primary Care Trust were invited to attend. The target audience included general practitioners, nursing, administrative and managerial staff and practices were incentivised to attend through the provision of deputising cover to assure protected educational time.

The format of this meeting on "Investigating Clinical Incidents" is summarised in Figure 4.3.

The meeting was introduced by the staff member from the National Patient Safety Agency. He presented an overview of patient safety issues in the National Health Service and summarised the aims and objectives of the Agency. This session was followed by a presentation from Professor Charles Vincent covering the theory and application of the investigation methodology. The principal investigator than presented a case from the series that has been conducted in primary care, to include the analysis of

care management problems and contributing factors. An officer from a medical insurance agency then presented some perspectives from a medico-legal perspective on reporting of incidents and participating in investigations, before the final open floor discussion of the issues that had been raised throughout the afternoon.

Figure 4.3. "Investigating Clinical Incidents" meeting

- An introduction to patient safety issues and to the National Patient Safety Agency
- An account of the theory behind the investigative approach and an overview of how it works
- An example of an investigation including an account of the clinical incident, the care management problems identified and the contributing factors that emerged
- An account of legal issues that might be relevant to investigation of clinical incidents, disclosures that might be made and the status of any new documentation emerging
- Interactive discussion on the investigation of adverse events using depth methods

Powerpoint (Microsoft Inc, Redmond WA, 1999) images of presentations were made available by presenters. The investigator made contemporaneous notes based on his observations during the event. The event organiser taped the interactive discussion and summarised key points on behalf if the investigator. Additional information was collated from a short evaluation form distributed and completed by participants at the close of the event.

4.2.4 Application with case vignettes

The principal investigator, with support from the originator of the investigative approach, hosted an interactive workshop for staff from local primary care organisations with an interest in patient safety or clinical governance.

The format of this meeting was:

a) An introduction to patient safety issues and to the investigative approach (originator of methodology)
b) An overview of how the approach works with an example from obstetric practice (originator of methodology)
c) Presentation of a vignette from a primary care case study and staged analysis in facilitated groups (principal investigator, originator)
d) Interactive discussion on the strengths and weaknesses of the approach (principal investigator)

A second abridged meeting adopting a similar format and methods was hosted subsequently for academic staff from the university department to which the principal investigator was attached.

The specific case vignettes featuring in the workshops were drawn from cases studies in primary care. The approach taken was to provide information on case histories to participants and to facilitate the application of a structured framework for considering contributory factors through small group work and shared feedback. The groups were introduced to the standard reporting format for the investigations and following the small group work, the findings were summarised and more general issues on the application of the investigative approach were discussed.

Flip chart materials were retained as documentary evidence of the outcomes of group work. Written notes were made, drawing on the investigator's observations of group work and on the content of interactive discussions

4.2.5 Conduct of case studies

4.2.5.1 Source of cases. At the outset, cases were identified by the principal investigator and involved incidents in the investigator's own practice. Six general practitioners linked to the academic department were invited to identify additional cases for investigation, and three agreed to do so. An additional three general practitioners

from the same locality, who had unresolved complaints relating to clinical incidents lodged with the Primary Care Trust, were also asked if they would like to participate in a structured investigation of the incidents with support from the investigator and one agreed to do so.

4.2.5.2 Ethics, confidentiality and consent. No ethics approval was sought. General practitioners were told that the investigative approach was being developed for use in primary care and community settings and that participation in the work would facilitate learning from clinical incidents. They were informed that the investigator hoped to build a portfolio of case studies that could be made available for learning and teaching purposes, but that no case study would be published without express consent of informants. The investigator requested no patient identifying information and all cases were fictionalised in research materials for the purpose of maintaining confidentiality.

4.2.5.3 Investigator training. The investigator was supported by staff based at the Clinical Risk Unit at University College London who originally developed the method for the investigation and analysis of incidents in healthcare. Familiarisation with the method was through communication with staff that had used the method and iteratively during the conduct of the case studies documented in this chapter.

4.2.5.4 Interview methods. Interviews with general practitioners took place in their surgeries or in the university office of the investigator. Informants were asked to summarise the clinical context of the case and what actually happened, to reflect on what might have gone wrong and then to consider reasons addressing patient related, practitioner related, practice related and any other factors. While remembering this overall structure the interviewer encouraged the informant to consider contributing causes wherever possible care management problems were mentioned. In some case studies, additional informants involved in cases were approached and interviewed by telephone or in face to face meetings.

4.2.5.5 Genesis of case studies. Notes were taken during interviews and case studies were drawn up immediately that interviews were completed. These manuscripts were returned to informants together with requests for additional information where detail

that appeared pertinent to the case was not available. Case studies were compiled in a standard format that included a section describing the clinical context and chronology of the incident, care management problems and their associated contributing factors. The detail of the care management problems and associated factors were agreed between the investigator and the general practitioner informant. Informants amended manuscripts and provided additional information when this was requested, available or obtainable. Finally, a synthesis of the incidents studied, care management problems identified and associated contributory factors were generated from the standardised case reports created.

4.2.5.6 Evaluation of process and outcome. Informants were encouraged to reflect on the process and product of the investigation, with particular reference to the "blame free" tenet, the face validity of the approach and the value of the investigation as a vehicle for learning. The investigator kept a reflexive diary throughout and made observations on process of likely relevance to adaptation of the method for primary care and on reactions and responses that reflected the understanding and acceptance of the method by the participants.

4.2.6 Development of the investigation guidance

A primary care consultation group was set up for the purpose of adapting and developing guidance for the investigation and analysis of clinical incidents in primary care settings. Group members were recruited following the first interactive workshop and included ten members of staff from local primary care organisations.

Drafts of the primary care guidance were produced in partnership with staff at the Clinical Risk Unit, drawing on the experience of the investigator in conducting case studies in primary care and with access to case reports from completed investigations. Successive versions of guidance were shared with the consultation group and were subject to iterative discussion.

The group considered the following criteria during its deliberations on the guidance:

1. Whether the overall purpose of the guidance was clear
2. Whether the scope was clear in relation to the incidents that could be investigated
3. Whether the context in which the guidance might be used was understood
4. Whether the theoretic foundations of the approach were explained adequately
5. Whether the evidence base for the application of the method was transparent
6. Whether the process was explained and easy to follow
7. How the findings emerge through analysis of raw materials
8. How recommendations for change might emerge from investigation

Notes were kept of meetings and interactions by electronic mail. Other insights were recorded in the investigator's reflexive diary. The final version of the guidance was made available for comment to all members of the panel and to the academic general practitioners who had agreed to help with the case study work.

4.3 RESULTS

The findings from the group meeting and interactive workshops are described and then the results from the case studies are presented with particular attention paid to the variety of contributing factors that emerged. The learning from this research informed subsequent development of the guidance for primary care investigations and modifications emerging through the consultation process are summarised in the final section.

4.3.1 Learning from group meeting

There was excellent attendance by primary care staff; seventy of the seventy three practices in the locality were represented by a general practitioner, usually with a practice manager and with some practices sending up to four additional staff.

There appeared to be great interest in the presentations. Numerous questions were asked most of which demonstrated insight into the agenda and an understanding of the issues. In particular, participants seemed to appreciate the analytic approach that underpinned the investigative approach, strongly identified with the systems focus and found the case presented - in particular the details of contributory factors- to reflect their own experience and understanding of various factors that operate together to underpin many clinical incidents. General practitioners also highlighted the difficulty of reconciling investigations into causes of incidents as represented in the approach, with the tort system, which seeks to identify and punish individual clinicians. They found the fact that the courts could request access to patient safety investigations, even those conducted within their own practices, disconcerting.

The evaluation questionnaire confirmed that respondents enjoyed the event and liked the way the material was presented, with most finding the event relevant and informative. Additional comments on the evaluation form broadly reflected the issues covered in the open discussion.

Overall the learning from the event indicated that the investigative approach carried a high level of face validity, but raised some issues on the likely acceptability of such investigations. There was identification with the value of participating in such investigations as a medium for learning, but concerns that they might become open to legal proceedings when care is shown to be substandard.

4.3.2 Findings from workshops

Participants in the first workshop included two audit facilitators, a prescribing advisor, three primary care managers, two professional development staff, a clinical governance

lead and a medical advisor. Three academic general practitioners attended the second workshop and three other academic staff.

Working groups grasped the approach quickly and assembled a range of insights on factors that might have been operating to underpin the clinical incident they were considering. The logical and systematic approach was appreciated and participants commented on way that the focus was away from blame and towards systems. One participant recognised that the so called care management problems are identified before the contributing factors, which potentially means that there is a discomfort zone that will still have to be crossed. It was also recognised that the approach as presented identified problems, but not solutions. If problems were identified there would be an obligation to seek to address them and would need to be a further stage to ensure that solutions are identified and improvements are implemented. Another participant was doubtful that practices would "sign up" to such investigations.

Like the service managers academic staff acknowledged the logic and face validity of the approach. Issues around interviewer effects, hindsight bias and difficulties around establishing causality were also raised. The latter applied at two levels. Firstly, informants could suggest a particular event or circumstance that might have been relevant, but assume, rather than know for sure that it had occurred. Secondly, even if an event occurred, they might be unable to argue for relevance unless there was independent evidence demonstrating a causal link. It was noted that the approach did not involve identifying or exploring the experiences of control groups and criteria to assess the validity of qualitative research were though to be most relevant to the evaluation of the method.

In summary, the approach had face validity and should be applicable in primary care settings, though care would be required in implementation to assure that informants understood the approach and did not feel uncomfortable as participants in investigations. Primary care managers recognised the obligation to identify appropriate remedial actions from the findings of investigations, seeing improvements in care delivery as the most relevant outcomes. Academics raised concerns about the internal validity of retrospective case based research in general and suggested that standards

applied to academic qualitative research might usefully be extended to incident investigations.

4.3.3 Case studies

Four general practitioners (of whom one was the investigator) contributed five cases between them. Three cases were from the principal investigator's own practice, one from an academic general practitioner and one from a general practitioner involved in an unresolved complaint being managed by the Primary Care Trust. One academic general practitioner did not find the time for assembling case materials within three months of agreeing to participate and another participated, but subsequently asked for their case to be withdrawn as they considered the scenario to be too sensitive to enter the public domain. One of the general practitioners involved in an unresolved complaint in which a patient had died, found the matter too difficult and sensitive to discuss with the investigator, and a second declined to participate and offered no explanation.

In two cases the investigator relied entirely on the general practitioner's account. In two others this was supplemented with information from a specialist nurse and a pharmacist respectively. In a third case, interviews were also conducted with a district nurse and a palliative care nurse.

The incidents featured and the care management problems identified are summarised in Figure 4.4.

Three of the incidents involved delayed diagnosis (Case 1, Case 3 and Case 4) and two were medication related problems (Case 2 and Case 5). All incidents involved acts of omission. In two cases, delays in diagnoses (Case 2, Case 4) might have affected the clinical outcome, in two cases delays in diagnosis led to more intensive clinical intervention (Case1, Case 4), one case led to unnecessary anxiety (Case 3) and one to unnecessary pain (Case 5).

Figure 4.4 Incidents studied and care management problems

Case 1. Delayed diagnosis of septic arthritis

a. Staff were unaware that the patient had been admitted to hospital
b. Staff were unaware that the patient had been discharged from hospital
c. There was delay in appreciating the seriousness of the patient's complaint

Case 2. Alleged negligence in prescription of post-coital contraception

a. The doctor did not provide adequate information to the patient
b. The pharmacist did not provide adequate information to the patient
c. The senior partner was unable to resolve the patient's concerns

Case 3. Delay in diagnosing ectopic pregnancy

a. The GP did not order a blood test which could have excluded a pregnancy related condition
b. The patient was not adequately followed up at the surgery
c. The patient was not adequately followed up at the hospital

Case 4. Delay in recognising oral cancer

a. The doctor wrongly assumed the patient's condition was self limiting
b. The patient did not contact the surgery for review even though her symptoms persisted
c. There was a delay between the doctor deciding to refer and the referral letter being sent

Case 5. Delayed analgesia in terminally ill patient

a. The doctor did not check the drug chart when he visited the patient
b. The doctor was unwilling to visit to reassess the patient
c. The doctor was unwilling to visit to sign off a drugs chart

The contributory factors which emerged across the case studies are presented thematically below:

4.3.3.1 Patient factors. Patient factors included issues around patients own interpretations of their symptoms, the perceived urgency of the presenting problem and/or difficulty coping, lack of confidence in the healthcare provider, effects of patients choosing their healthcare management options, communication issues including language and hyperbole, failure to follow instructions for various reasons,

including self neglect of lack or assertiveness and practical issues such as limited mobility or concomitant mental health problems.

4.3.3.2 Individual staff factors. These included examples where there might have been deficits in knowledge or skills, errors of judgement, or slips resulting in omissions. Errors of judgement and slips resulting in omissions were identified more often than knowledge or skills deficits. Time pressures and emotional responses also featured prominently and there was one example of a behaviour that was underpinned by medico legal considerations. Interactions between patient level factors and individual staff responses were commonly observed; understandably the response of the healthcare provider was influenced by the concerns, affect, and appearance of the patient, but not always in a way that led to a constructive outcome.

4.3.3.3 Task factors. There were a number of examples where the failure to execute a particular task might have contributed to the adverse outcome for the patient. Practical difficulties were often cited, either as reasons for protocol deviations, or for particular courses of action, which ultimately might have led to adverse outcomes. In one case an inadequate examination was attributed to difficulties in examining a patient in a home environment. In another a general practitioner refused to conduct a home visit, because his patient had moved some miles away from the practice. In other cases, the justification for protocol deviations was harder to find, for example, discharging a patient with a postoperative fever. Finally, there were a group of factors related to information management that affected patient care, where written information was either not available, or inappropriate to the task.

4.3.3.4 Team factors. Communication between staff in primary and in secondary care, between doctors and community staff, and between doctors in primary care all featured in case study analyses. The primary-secondary care issues were mainly well recognised communication difficulties around admission and discharge. Unfortunately there were also many examples of communication difficulties between general practitioners, community nurses and community pharmacists, which might have contributed to adverse outcomes for patients. Even within practices, issues of communication between GP partners occasionally arose as an issue.

4.3.3.5 Work environment factors. Workload and throughput issues featured prominently amongst general practitioners where large patient list sizes, high demand for "urgent" appointments, issues around managing administrative workload and home visit requests, led to time pressures and personal stress. These work environment features could influence both the conditions under which patients' needs were assessed and the potential for assuring continuity of care. Related to workload and throughput, were issues around out of hours of availability and appropriate hand over arrangements. General practitioners switching over to deputising services and lack of availability of palliative care teams at weekends, led to situations where other healthcare professionals were unclear how to proceed, or where the limits of responsibility lay. In community nursing, staffing and supervision emerged as an issue in one case study, where a team were suffering staffing shortages and dependent on new staff seconded from elsewhere. Communications issues emerged as influenced by factors at the level of work environment. Part time working and/or lack of meeting space in premises constrained communication between general practitioner partners In some cases district nurses worked from a different site to GPs, precluding opportunities for more informal communication. Pharmacists often work alone, and even though a professional advice line is available to them, this is a nine to five service only. Failures in communication from hospitals were often interpreted as lack of attention to detail associated with workload and throughput.

4.3.3.6 Organisation and management problems. Overarching themes in this section included managing demand from patients accessing general practice, increasing administrative workload, use of locums in general practice, recruitment and retention issues in community nursing, use of evidence in clinical care, provision of out of hours and interdisciplinary care. Configuration of services also featured especially differences between teams or hospitals in the way they operate and the influence of the historic and managerial differences between general practice, and community services, that affect the way they interact.

4.3.4 Findings on process and outcome

Informants tended to focus on the immediate circumstances surrounding an event and needed to be prompted to consider higher level factors. Some nevertheless provided spontaneous and valuable narratives, though not always in the sequence suggested by the investigative model, implying a necessity for sensitivity, flexibility and rigour by the interviewer. Informants reported that they found participation in the investigations instructive, but many sought reassurances on the context in which the work was being done. A concluding meeting with general practitioner informants in which the case study report was discussed, reinterpreted and amended was accommodated as an important stage in the process of documenting and analysing the circumstances surrounding adverse incidents.

4.3.5 Consultation on guidance

The consultation panel agreed that the guidance should be constructed to identify with the pragmatic and action orientated culture of primary care, above demonstrating the academic excellence of the instrument. In the earliest drafts, reflecting most closely the original instrument, some of the language was perceived to be too difficult and some of the instructional material to be over complex, with unnecessary repetition. As such, the main adaptations made to the generic instrument related to the order in which materials were presented, an expansion in the detail on the practicalities of conducting investigations in primary care situations, a reduction in the volume of theoretical material and a simplification of the language used.

After further consideration of its likely conditions of use, it was felt that the instrument should not be too restrictive in its application. The final version was written as a generic document that might be used by general practitioners, practice managers, health service managers or researchers.

Particular attention was paid to information sources that might be available in primary care settings, the contexts in which investigative work might take place, how the period of review might be framed and how to interview staff in a constructive and non-judgmental way. The panel also suggested three additions to the instrument; a one page

"how to do it" card, information on constructing action plans from investigations, and a collection of worked examples.

These additional materials were included in due course and the guidance emerging from the consultation appears in Appendix 9.

4.4 DISCUSSION

4.4.1 Summary of main findings

There were good levels of insight amongst primary care staff on issues surrounding learning from clinical incidents and powerful identification with the principle of moving from blame to a more complex understanding of cause, but with reservations about the medico legal implications of participating in such investigations. Workshop groups grasped the investigative approach quickly and appreciated the value of a systematic approach. The main concern expressed with the method was the need to identify "care management problems" before proceeding to causes, as the former would be a sensitive area for informants. The need for mechanisms for identifying solutions and implementing changes was also identified. Academic stakeholders raised issues relating to validity and reliability of the methodology as applied in accident investigations and pointed to criteria for evaluating qualitative research as of relevance.

Three approaches were used to identify incidents for depth investigations. The principal investigator identified incidents in his own practice, academic colleagues were asked to assist, and colleagues elsewhere in the locality who were involved in unresolved complaints with the Primary Care Trust were invited to participate. Only a half of the academic general practitioners approached agreed to contribute cases for investigation and of three that did agree, one was never interviewed and one asked for their case to be withdrawn on grounds of sensitivity. Relatively few general practitioners come to the attention of the Primary Care Trust with unresolved complaints that justify detailed investigation, and these cases are more often serious and can involve professional and

medico-legal issues. This might have fuelled reluctance to participate in investigations voluntarily amongst two of the three general practitioners invited to do so.

The case study work demonstrated that the approach was valuable and the framework applicable to the investigation and analyses of incidents in the primary care setting. The contributory factors framework that included patient factors, staff factors, team communication, work environment and organisation and management factors as areas influencing patient safety could be extended without modification to primary care. The framework was particularly valuable to the interviewer, in considering whether different issues operating at different levels might have been cogent in a particular case, and in this respect was used as a mental checklist as interviews were conducted. Key skills would be needed of an interviewer conducting this type of work including sensitivity, flexibility and commitment to the underlying theoretic framework.

Guidance for primary care investigations was developed from a protocol for the investigation of clinical incidents published by Vincent and colleagues (Vincent *et al.*, 1999). Translational work was required and adaptations were made to create a generic instrument for use in primary care settings. The panel subsequently suggested three additions to the instrument; a one page summary, information on constructing action plans and a collection of worked examples. These changes were added to a version for use in service settings.

In conclusion the approach demonstrated high levels of face validity amongst primary care stakeholders, and staff from primary care organisations recognised applicability for investigations in primary care. Feasibility issues were raised, but did not preclude the conduct of a series of case studies, that further demonstrated the utility of the method. For more rigorous use and for use in formal research settings, further methodological issues would need to be considered and these are discussed below.

4.4.2 Relevance to application of method in research and development

The process of interviewing individual staff was a highly skilled task. The pattern of documenting chronology, identifying problems and looking for underlying causes was helpful provided informants' tendencies to move across these concepts were recognised and used constructively during interviews. The sequence provided a useful background structure against which to check and return as the interview progressed. The contributory factors framework was used as a guide to prompting, ensuring that various aspects were considered, but with care taken to ensure that the interviewer did not lead the informant to provided biased information on factors that they thought might have contributed to the evolution of the incident studied. This stage of the interview was more challenging than the process of reconstructing the chronology and cognitive interviewing approaches (Memon and Koehnken, 1992) were employed to assist the informant in picturing scenarios, care management problems and possible contributory factors. The latter involves encouraging informants to visualise events and circumstances, to report details freely without considering relevance, to reflect on incidents from different perspectives and to fast forward or run narratives in reverse.

The conduct of investigations in primary care was necessarily different to that which might be conducted in hospital settings. Medical records tended not to be detailed and included written and computerised notes. The narrative provided by the patient's general practitioner was usually central to managing any investigation as the knowledge of the general practitioner informant often far exceeded anything that could be gleaned from medical records. The fact that general practitioners had often known patients for many years, however, led to a particular issue in constructing case chronologies. In hospital based cases, admission and discharge provide a timeframe for investigation, which is not available in primary care. Indeed the time frame for interactions, for the emergence of antecedents and consequences may be much longer in primary care. A delayed cancer diagnosis for example, might evolve as an incident over many months. While equivalent situations might arise in hospital settings, most work with depth investigations has been in departments such as accident and emergency or obstetrics and often in the case of rapidly evolving scenarios.

Two of the case studies in this research were compiled entirely on the basis of information provided by general practitioners. However, new perspectives frequency emerged as investigations moved beyond general practitioner informants to include other staff involved in particular cases, such as district nurses and pharmacists. Operationally, investigations became more challenging at this point. There is little by way of cross referencing between records held by general practitioners, district nurses and pharmacists, so recreating an accurate chronology required some care. Also skill was required to manage the what, how, why sequence across various informants and thereafter to create a coherent and accurate account of a case. The latter is not unique to primary care, though the pattern of different health care professionals working independently with a single patient is rather different to a hospital based situation where different health care professionals are more likely to be working alongside each other with a single patient.

4.4.3 Towards a robust research design for a primary care study

The research conducted here suggests that the investigative method described by Vincent *et al* (1999) is an acceptable and feasible approach to investigating clinical incidents in primary care settings. Also, key practical considerations were identified, that will apply when using the approach in a different environment to that in which it was originally developed. In a previous chapter the organisational accident causation model was evaluated against a set of nine criteria assembled to assess the performance of accident investigation techniques (Benner, 1985; Kirwan, 1992a, 1992b). While OACM performed well against these criteria, applied in its original form it could fall short of the expectations of qualitative researchers. Two particular areas that would need to be more carefully addressed in a definitive research study would be validity of the data collection and analysis processes and the context in which cases were identified and selected for investigation and analysis (Popay and Rogers, 1998).

Staff involved in one of the interactive workshops raised issues around the validity of data collection methods. It was previously argued that the theoretical roots and systematic approach helped assure validity and consistency. Two additional approaches

to improving validity emerged in the research described in this chapter. Firstly, engaging and interviewing multiple informants could both improve confidence in elements of a story and demonstrate elements that might be subject to differential recall or interpretation. Secondly, checking materials back with informants, a commonly used procedure for validation in qualitative research provided an opportunity to check and challenge recall and interpretation of events. Although there were no formal replicate studies in the developmental research described in this chapter, the work with case vignettes demonstrated that different individuals or groups of individuals could examine the same case materials and come up with differences in detail on their interpretation of relevant contributing factors. This was another area that would require further consideration in a research study and might appropriately be addressed through replicate analyses with discussion, an approach that is used in qualitative research, but less so in accident investigations (see Chapter 3).

The cases investigated in this chapter came from a range of sources. Service staff may be reluctant to bring attention to incidents involving patients in their care. The pool from which the case studies are drawn and the extent to which they are representative of cases occurring in primary care are unknown. They were also quite heterogenous, including delayed diagnoses and medication related problems, whereas a more closely defined subgroup may be support more consistent findings in a research study. There are some examples of depth approaches being applied to incidents that were identified through broader surveillance systems such that quantitative information was complemented by detailed qualitative information from a nested case series (Boreham *et al.*, 2000; Eagle *et al.*, 1992). The challenges of building a case series of investigations in primary care, and the added value of assembling a series that can help address a particular area of concern thus informed the hybrid design described in this thesis. As such, the next chapter introduces a study based in a medical admissions ward and is designed to identify older patients with medication related problems, medication related admissions and preventable medication related admissions. The study provides quantitative demographic and clinical information on patients with medication related problems and provides a study population for subsequent depth inquiries.

5. MEDICATION RELATED ADMISSIONS IN OLDER PEOPLE

5.1 INTRODUCTION

Many older adults are prescribed complex treatment regimes to alleviate the effects of medical problems and degenerative conditions. More than half of all older people take regular medications and of those over 75 years, over a third are taking four or more drugs (Department of Health, 2000b).

The range and effectiveness of medication available has increased rapidly over the last decade, demanding careful assessment and realistic prescribing. Polypharmacy increases the risk of adverse drug reactions and age related changes in drug handling and target organ sensitivity makes older patients more susceptible to drug effects (National Prescribing Centre, 2000). Patients experiencing social isolation, deterioration in vision, memory and manual dexterity are also at risk from untoward drug effects due to errors in the self administration of appropriately prescribed drugs (Wendt, 1998).

Failure to treat common conditions with drugs that could ameliorate health conditions or prevent complications is also common in older people. For example, the use of daily aspirin amongst patients with coronary heart disease reduces mortality from this cause, but many patients do not receive the drug (NHS Centre for Reviews and Dissemination, 1996; King *et al*, 1995). The risk of stroke amongst patients with atrial fibrillation is reduced by the use of warfarin, but treatment rates are low and decrease as age increases (Atrial fibrillation investigators, 1994; O'Connell *et al*, 1996; Sudlow *et al*, 1997). Despite the high prevalence of hypertension in older people and the clear benefits of effective treatment, only three quarters of cases are detected, three quarters of those detected are treated and only half of those have their blood pressure controlled (Mulrow *et al*, 1994; Duggan *et al*, 2001).

This chapter describes research conducted to assess the size and nature of the problem of medication related admissions in older people. The epidemiological base provides the context for further research into causes that is developed in the chapter that follows.

The studies are formally linked as the preventable medication related admissions identified in the quantitative study comprise the sampling frame for depth investigation in the case studies. Although the primary purpose was to provide a sampling frame for case based research in primary care, this study is also set in the context of similar studies conducted in a range of settings to study medication related admissions. These have informed the method, the focus and the scope of the study described which is designed to identify the proportion of older patients admitted as a result of adverse drug events, including therapeutic failures, and the extent to which these might have been preventable.

5.2 COMPARATIVE LITERATURE

Adverse drug reactions include any unexpected unintended, undesired, or excessive response to a medicine used in an accepted therapeutic dose (ASHP, 1998) and are typically assessed in studies of hospitalisation due to drug effects. Adverse drug events include any injury from a medicine or from lack of an intended medicine (ASHP, 1998) and are assessed in some but not all studies. Adverse drug reactions are included, but so are the consequences of lack of adherence including under dosage and over dosage effects. Some, studies aim to assess whether hospitalisation due to a drug event was potentially avoidable; this assessment may be applied to adverse drug reactions, or to all adverse drug events.

Lazarou *et al.* (1998) conducted a review and meta-analysis of 39 prospective studies of adverse drug reactions in US hospitals and estimated a rate of serious events of 6.7% and of fatal events was 0.32% amongst hospitalised patients. Wiffen *et al.* (2002) subsequently conducted a review of the international literature on adverse drug reactions, including 108 primary studies using prospective or retrospective methods and involving 412,000 patients overall. This author estimated a rate of 7% amongst

hospitalised patients in Europe and the United Kingdom, with almost half of these patients having been admitted because of adverse drug reactions. In a large study conducted in the United Kingdom and involving review of 18,820 patients, Pirmohamed *et al.* (2004) found adverse drug reactions accounted for 5.2% of admissions, and were associated with a case fatality rate of 0.15%. The authors also investigated the avoidably of the adverse drug reactions and concluded that 72% could have been avoided, a finding that has major implications for medication management in primary and community care settings.

Einarson (1993) and Roughead *et al.*, (1998) summarise the findings of studies of medication related hospital admissions from primary and community care and include data on adverse drug reactions and other adverse drug events. The earliest review (Einarson, 1993) included 49 reports from 37 studies, in which 69,187 hospital admissions were investigated to detect 2897 adverse drug reactions. Across the entire series, the proportion of hospital admissions caused by adverse drug reactions was between 0.2% and 21.7 % with a weighted average of 5.1%. Einarson (1993) also summarised the findings of a sub group of studies that estimated the proportion of hospital admissions caused by non compliance with prescribed drug regimens. In this series, drawing on 4571 admissions and 205 cases of non compliance, the proportion of hospital admissions caused by non compliance was between 2.9% and 19.5% with a weighted average of 6.5%. Roughead *et al.* (1998) included only Australian studies. In this series, based on a broad definition of adverse drug events that included adverse drug reactions, non compliance and therapeutic failures, 2.4% to 3.6% of admissions were medication related, and between 32% and 69% of medication related admissions were judged definitely or possibly preventable.

Another review of studies of hospitalisations due to drug effects was conducted to estimate the prevalence of preventable medication related admissions (Winterstein *et al.*, 2002). Using a broad definition of adverse drug events that included therapeutic failures, the median prevalence in fifteen studies was reported as 4.3%, corresponding to a preventability rate of 59% of medication related admissions. The review was restricted to studies published before 1999 and only two of the studies were from the UK, but a recent study based on screening of 4093 admissions to a medical admissions unit at a university hospital in the United Kingdom generated similar results (Howard *et*

al., 2003). In this study 6.5% of admissions were judged to be medication related and 67% of these to have been preventable, and attributed to problems with prescribing, monitoring or adherence in primary care settings.

None of the studies described were specifically directed towards studying medication related admissions in older people, though Einarson (1993) and Roughead *et al.* (1998) describe higher rates of medication related admissions with age. Seven studies were identified that have generated data on medication related admissions in older people (Chan *et al.*, 2001; Malhotra *et al.* 2001, Cunningham *et al.* 1997, Hallas *et al.* 1991, Pouyanne *et al.*, 2000; Raschetti *et al.* 1999; Colt and Shapiro, 1989). Medication related admission rates varied between 2.4% and 30.4%, but amongst the four studies that were methodologically closest to the one proposed, rates were between 3.4% and 7.5% (Malhotra *et al.* 2001, Cunningham *et al.* 1997, Hallas *et al.* 1991, Chan *et al.* 2001) and preventability fractions were reported between 0.53 (Chan *et al.*, 2001) to 0.75 (Hallas *et al.*, 1991).

5.3 METHOD

The specific objectives for the quantitative research were: (1) to measure the proportion of acute medical admissions in people aged 65 years or more that are medication related; (2) to describe the types of the problems that occur; (3) to identify the predictors of medication related problems and associated admissions (4) to assess the impact of medication related admissions on usage of hospital beds.

Ethics committee approval for the study was received from the hospital in which the research was based and from five surrounding local research ethics committees.

5.3.1 Study setting

The study setting was the medical admission unit of a single north London hospital accepting approximately 3,600 acute medical admissions every year of which 55% (2000) were patients aged 65 years or older. The majority of patients are admitted from two coterminous Primary Care Trusts covering inner city populations and with most of the remainder admitted from three other geographically close Primary Care Trusts. Patients requiring hospitalisation are referred from general practice, accident and emergency or domiciliary visits to an admissions ward that is covered by clinical teams on rotation. They are assessed and stabilised, then transferred to medical and care of the elderly beds, usually on the next working day, according to patient need and bed availability. Short stay patients remain under the care of the admitting consultant; patients requiring a longer stay may be transferred to the care of a consultant with a relevant specialist interest.

5.3.2 Study design

A cross sectional observational design that draws on the methodology of occurrence screening studies was used (Brennan *et al*, 1991; Wilson *et al*, 1995). A hospital pharmacist was based on the admissions ward of the hospital over a three month study period between September 5th and December 4th 2002 for the purposes of conducting the research. The pharmacist conducted a daily round (excluding weekends) reviewing the admissions notes, referral letters and drug charts of every patient of 65 years or more (Appendix 10). Multiple admissions of individuals during the study period were counted as separate episodes except where readmission occurred within 48 hours in which case only one episode was counted.

Demographic information, presenting problems, previous diagnoses and drugs history was recorded and possible medication related problems were assessed against eight predefined criteria (Strand *et al*, 1990). Patients screening positive were subject to detailed review by a specialist registrar who examined case notes, chased outstanding test results and checked details with patients. Information assembled by the registrar was collated and presented to a multiprofessional panel for final decisions on attribution and preventability (Taxis *et al*, 2002).

Figure 5.1: Categories of medication related problems

1. The patient has a medical condition that requires a drug but the patient is not receiving a drug for that indication
2. The patient has a medical condition for which the wrong drug is being taken
3. The patient has a medical condition for which too little of the correct drug is being taken
4. The patient has a medical condition for which too much of the correct drug is being taken
5. The patient has a medical condition resulting from an adverse drug reaction
6. The patient has a medical condition resulting from a drug-drug, drug-food or drug-laboratory interaction
7. The patient has a condition that is the result of not receiving a prescribed drug
8. The patient has a condition that is the result of taking a drug for which there is no valid indication

From: Strand *et al.*, 1990

5.3.3 Specification of medication related problems

Strand *et al* (1990) described a medication related problem as an undesirable patient experience that involves drug therapy that actually or potentially interferes with a desired patient outcome. For an event to qualify as a medication related problem, at least two conditions must exist: (1) a patient must be experiencing or must be likely to experience disease or symptomatology and (2) these conditions must have an identifiable or suspected relationship with drug therapy. The criteria allow for situations where a patient suffers symptoms as a result of drugs taken (e.g. dizziness on an antihypertensive agent) and for symptoms because drugs have not been administered (e.g. a stroke in an individual who should have been on an antihypertensive agent, but was not). Within the classification all medication related problems can be reduced to one of eight categories, which provide pointers to interventions that could have averted the adverse outcome (Figure 5.1).

The pharmacist was trained through a one month on the job run in period. A formal validation exercise of pharmacist versus specialist registrar screening of admissions was conducted before the study was initiated. A pharmacist-pharmacist comparison was made subsequently to measure the replicability of pharmacist screening. In an

initial pharmacist-specialist registrar comparison the level of agreement on whether medication related problems was present was moderate at Kappa=0.47. In a second pharmacist-specialist registrar comparison that followed discussion of discrepancies this increased to Kappa=0.78. The sensitivity of the pharmacist screening compared to the registrar was 100% and the specificity was 75% in this exercise. The level of inter-rater agreement for a pharmacist-pharmacist comparison run towards the end of the study was Kappa=0.76.

5.3.4 Judgement of attribution and preventability

The registrar collated information from medical records, test results and interactions with patients and made decision on whether an admission could be attributed to a medication related problem. Cases were classified as medication related admissions when a disease, symptom or abnormal test attributed to the drug was thought to have contributed entirely or in part to the reason for admission. A provisional judgement of preventability was also made where the registrar judged the outcome could have been foreseeable and that the cause of the drug therapy problem was ameliorable (Hallas *et al*, 1990).

Case summaries were produced for all patients with adverse outcomes caused by medications or their absence and then presented to a multidisciplinary panel comprising a consultant geriatrician, a senior pharmacist and a general practitioner (Taxis *et al*, 2002). The panel reviewed the information available, discussed the circumstances surrounding the case in the context of their knowledge of the medications involved, the patient's medical conditions and current practice in primary and secondary care. A final decision was then taken by consensus on the attribution of admissions to medication related problems and on the preventability of the medication related problems.

The assessment of attribution at this stage included a detailed consideration of evidence for a causal relationship between the medication related problem and the reasons for admission underpinned by a set of criteria described by Naranjo *et al.*, (1981) and adapted by Stanton *et al.*, (1994). An additional framework developed from previous

research and described by Dartnell *et al.*, (1996) informed the discussion of preventability.

Figure 5.2: Criterion for assessing of attribution and preventability of medication related admissions

Medication related admission (Hallas et al 1990)

1. The medication related problems were the main reason for admission, or contributed significantly to the reason for admission

Assessment of preventability (Hallas et al 1990)[1]

2. Given the drug therapy problem, the drug related morbidity would have been foreseeable and
3. The cause of the drug related morbidity was reasonably controllable within the context and objectives of treatment

Assessment of causality (Naranjo 1981, Stanton et al 1994)[2]

4. Presence of a known adverse drug reaction or toxic reaction or effect of inadequate treatment
5. Presence of a reasonable temporal relationship between commencement of the drug therapy and the onset of the adverse reaction
6. The adverse reaction disappeared on reducing or stopping the drug or after the administration of a suitable antagonist
7. The symptom or event could not be explained by any other known condition of the patient
8. Laboratory tests showed levels outside the therapeutic range or metabolic disturbances were responsible
9. The patient had had the same reaction following previous exposure to the same or a similar drug

Assessment of preventability (Dartnell et al 1996)[2]

10. The suspected drug was judged to be contraindicated given the patient's clinical history and other medications
11. The drug was unnecessary or an alternative safer option could have been prescribed given the patient's history and other medications
12. There is good evidence that a medication which the patient is not taking could have averted the outcome
13. The dosage used by the patient was different from accepted recommendations
14. The patient had not been counselled adequately on drug use and was unclear on dose or frequency of administration
15. It is unlikely that the patient's illness would have precipitated this particular admission irrespective of drug therapy

[1] Criteria applied by registrar
[2] Criteria applied by multidisciplinary panel

5.3.5 Justification for sample size

Figure 5.3 shows the precision of the estimate of the proportion of admissions, which are medication related, under various assumptions, and the number of cases per week, which might be identified in the study setting. Calculations assumed 2000 patients 65 years or more admitted per year and 500 during a study period of three months. If the proportion of medication related admissions in patients 65 years were towards the higher end, the study would generate 4 - 5 cases per week, or about 50 cases in total, of which half might be judged preventable.

Figure 5.3: Precision of estimate of medication related admissions and cases per week identified by occurrence screening process in place over twelve weeks.

Proportion	95% CI	Cases/week -all
3%	1.4%-4.6%	1.2
6%	3.8%-8.2%	2.3
18%	14.4%-21.6%	6.9

5.3.6 Coding and data management

Information collected by the pharmacist was coded onto a separate coding sheet, together with the attribution and preventability classifications derived from the registrar and consensus panel. The original data collection sheets were reviewed to assure that Strand coding was complete and systematic. Amongst patients for whom a medication related problem was recorded a second coding sheet was completed to record the medications involved and the associated morbidity. The International Classification of Disease (WHO, 1994) was used to code presenting problems and previous morbidity, and drugs were coded according to British National Formulary (British Medical Association and Royal Pharmaceutical Society, 2002) section headings.

Data was entered onto SPSS (SPSS Inc, Chicago IL, 1999) and checked against coding sheets for accuracy. Age at admission, in years, was calculated from date of birth and admission date. A new variable was derived from the Strand Classification incorporating failure to prescribe, under dosage and failure to use prescribed drugs as

"under treatment", retaining "adverse reactions" and incorporating over dosage, drug-drug interactions and inappropriate use as "over treatment".

Additional data was subsequently downloaded from the hospital Patient Administration System. For medical admissions during the study period and within the specified age range a file was created that included fields for hospital number, date of admission, date of birth, gender, length of stay and outcome of stay. This PAS derived database and the study database were merged using the hospital number to create two overlapping sets of records of which 322/409 (79%) study records and 322/486 (66%) PAS derived records matched.

Range and consistency checks were conducted across all variables and aberrant data was reviewed and corrected.

5.3.7 Data analysis

The representativeness of the study sample was assessed by comparing the age and gender distributions in the study sample with that in the Patient Administration System data using the z test (Kirkwood, 1988).

The characteristics of the study sample were enumerated by generating statistics on the following demographic and clinical variables using the frequencies option in SPSS and calculating 95% confidence intervals as 1.96*sqrt(p(1-p)/n):

Demographic variables: Gender and age classified as patients 65-<70 years, 70-<80 years, 80-<85 years, 85-<90, 90-<95 years, 95 years or more.

Clinical variables: Number of admission diagnoses classified as 1,2 3 or more; number of previous diagnoses classified as 0,1,2,3,4,5,6 or more and number of drugs on admission classified as 0,1,2,3,4,5,6,7,8,9 or more.

The pattern of medication related problems and associated admissions were enumerated by generating statistics on the following outcome variables using the frequencies option in SPSS and calculating 95% confidence intervals as 1.96*sqrt(p(1-p)/n):

Medication related problems: Number of patients with medication related problems; number of patients with medication related problems according to Strand classification; class of drugs involved; associated outcomes; number of patients with medication related problems due to under treatment, adverse reactions and over treatment;

Medication related admissions: Number of patients with medication related admissions; number of patients with medication related admissions according to Strand classification; class of drugs involved; associated outcomes; number of patients with medication related admissions due to under treatment, adverse reactions and under treatment;

Preventable medication related admissions: Number of patients with preventable medication related admissions; number of patients with medication related admissions according to Strand classification; class of drugs involved; associated outcomes; number of patients with preventable medication related admissions due to under treatment, adverse reactions and under treatment.

The t-test was used for two-way comparisons where data was continuously distributed and ANOVA for multiple comparisons or trends. Chi squared and Chi squared for trend was used for comparisons between proportions (Kirkwood, 1988).

5.3.8 Development of predictive models

Stage 1:

Interrelationships between the gender, age and clinical variables were explored by tabulating admission diagnoses, previous diagnoses and drugs on admission across age and sex strata. Chi squared for trend was used to test for trend with age in males and in females. Interrelationships between the gender, age and medication related outcomes

were also explored by tabulating numbers and proportions of medication related problems, medication related admissions and preventable medication related admissions across age and sex strata. Chi squared was used to test for trend with age in males and in females. Finally, interrelationships between admission diagnoses, previous diagnoses, drugs on admission and medication related outcomes were examined. Chi squared was used to test for trend with number of admission diagnoses, number of previous diagnoses and numbers of admission drugs.

The following logistic regression models were then specified, for medication related problems (MRP), medication related admissions (MRA) and preventable medication related admissions (PMRA), drawing on demographic and clinical variables, but excluding number of admission diagnoses (as a probable co-variable, rather than predictor of study outcomes):

$MRP=B_0+B_1(\text{gender})+B_2(\text{age group})+B_3(\text{previous diagnoses})+B_4(\text{admission drugs})$

$MRA=B_0+B_1(\text{gender})+B_2(\text{age group})+B_3(\text{previous diagnoses})+B_4(\text{admission drugs})$

$PMRA=B_0+B_1(\text{gender})+B_2(\text{age group})+B_3(\text{previous diagnoses})+B_4(\text{admission drugs})$

Stage 2:

Interrelationships between the gender, age and medication related outcomes relating to under treatment, adverse reactions and over treatment were explored by tabulating numbers and proportions of medication related problems, medication related admissions and preventable medication related admissions by age, sex, number of admission diagnoses, number of previous diagnoses, number of admission drugs. Chi squared was used to test for trend.

The following logistic regression models were specified, drawing on demographic and clinical variables, but as above, excluding number of admission diagnoses (as a probable co-variable, rather than predictor):

$MRP\ (\text{under treatment})=B_0+B_1(\text{gender})+B_2(\text{age group})+B_3(\text{previous diagnoses})+B_4(\text{admission drugs})$

MRA(under treatment)=B_0+B_1(gender)+B_2(age group)+B_3(previous diagnoses)+B_4(admission drugs)

PMRA(under treatment)=B_0+B_1(gender)+B_2(age group)+B_3(previous diagnoses)+B_4(admission drugs)

And

MRP (adverse reaction)=B_0+B_1(gender)+B_2(age group)+B_3(previous diagnoses)+B_4(admission drugs)

MRA(adverse reaction)=B_0+B_1(gender)+B_2(age group)+B_3(previous diagnoses)+B_4(admission drugs)

PMRA(adverse reaction)=B_0+B_1(gender)+B_2(age group)+B_3(previous diagnoses)+B_4(admission drugs)

And

MRP (over treatment)=B_0+B_1(gender)+B_2(age group)+B_3(previous diagnoses)+B_4(admission drugs)

MRA(over treatment)=B_0+B_1(gender)+B_2(age group)+B_3(previous diagnoses)+B_4(admission drugs)

PMRA(over treatment)=B_0+B_1(gender)+B_2(age group)+B_3(previous diagnoses)+B_4(admission drugs)

5.3.9 Bed use and mortality

Descriptive data on the length of stay and the outcome of stay were generated by age and gender for patients with medication related problems, medication related

admissions and preventable medication related admissions respectively. Total bed days were calculated for patients in the study sample, for those with medication related admissions and those with preventable medication related admissions.

5.4 RESULTS

5.4.1 Sample selection

Four hundred and eighty five acute medical admissions were recorded on the hospital Patient Administration System (PAS) during the study. The pharmacist screened four hundred and nine patients during the same period, corresponding to 84% of the total.

Eighteen study patients had been admitted twice and one three times during Sept 5th – Dec 4th. Twenty eight patients from PAS were recorded as having been admitted more than once during the same period.

The mean age of the study patients was 79.9 (95% CI, 79.1-80.7) years compared with the mean age of patients from PAS as 79.4 (95% CI, 78.7-80.1) years ($z = 1.03$, $p > 0.05$). 31.1% (95% CI, 26.6-34.6%) of study patients were male and 36% (95% CI, 31.6-40.2%) of patients from PAS were male ($z = 1.57$, $p > 0.05$).

5.4.2 Demographic and clinical characteristics of study sample

The demographic and clinical characteristics of the study sample are summarised in Table 5.1.

About seventy percent of the sample were eighty years old or more and twenty seven percent were ninety years old or more. Sixty nine percent of the sample was female patients and female patients were older than male patients (81.0 versus 77.5 years; $t = -4.20$, $df = 1$, $p < 0.0001$).

Table 5.1: Characteristics of study sample

Variable		number	percentage	95% CI lower limit	95% CI upper limit
Sex					
	Male	127	31.1%	26.6%	35.6%
	Female	282	68.9%	64.4%	73.4%
Age in years					
	<70yrs	50	12.2%	9.0%	15.4%
	70-<80yrs	69	16.9%	13.3%	20.5%
	80-<85yrs	89	21.8%	17.8%	25.8%
	85-<90yrs	89	21.8%	17.8%	25.8%
	90-<95yrs	63	15.4%	11.9%	18.9%
	95yrs or more	49	12.0%	8.8%	15.1%
Number of admission diagnoses	1	195	47.7%	42.9%	52.5%
	2	134	32.8%	28.2%	37.4%
	3 or more	80	19.6%	15.8%	23.4%
Diagnostic Groups	Circulatory	141	34.5%	29.9%	39.1%
	Respiratory	129	31.5%	27.0%	36.0%
	NEC	69	16.9%	13.3%	20.5%
	Genitourinary	68	16.6%	13.0%	20.2%
Number of previous diagnoses	0	20	4.9%	2.8%	7.0%
	1	49	12.0%	8.8%	15.1%
	2	89	21.8%	17.8%	25.8%
	3	88	21.5%	17.5%	25.5%
	4	65	15.9%	12.4%	19.4%
	5	42	10.3%	7.4%	13.2%
	6 or more	56	13.7%	10.4%	17.0%
Diagnostic Groups	Circulatory	270	66.0%	61.4%	70.6%
	Respiratory	116	28.4%	24.0%	32.8%
	Endocrine	107	26.2%	21.9%	30.5%
	Musculoskeletal	88	21.5%	17.5%	25.5%
Number of medications on admission	None	19	4.6%	2.6%	6.6%
	1	29	7.1%	4.6%	9.6%
	2	47	11.5%	8.4%	14.6%
	3	51	12.5%	9.3%	15.7%
	4	46	11.2%	8.1%	14.3%
	5	51	12.5%	9.3%	15.7%
	6	42	10.3%	7.4%	13.2%
	7	34	8.3%	5.6%	11.0%
	8	37	9.0%	6.2%	11.8%
	9 or more	53	13.0%	9.7%	16.3%
Drug classes					
	Cardiovascular	286	69.9%	65.5%	74.3%
	Nervous system	182	44.5%	39.7%	49.3%
	Respiratory	112	27.4%	23.1%	31.7%
	Endocrine	111	27.1%	22.8%	31.4%

The average number of admission diagnoses was 1.78 (95% CI 1.69–1.87). The most common admission diagnoses were diseases of the circulatory system (34.5%; 95% CI 29.9-39.1%), diseases of the respiratory system (31.5%; 95% CI 27.0-36.0%), symptoms and abnormal findings not elsewhere classified (16.9%; 95% CI 13.3-20.5%) and diseases of the genitourinary system (16.6%; 95% CI 13.0-20.2%). The average number of previous diagnoses was 3.18 (95% CI 3.06-3.42).

The most common coded previous diagnoses were diseases of the circulatory system (66%; 95% CI 61.4-70.6%), diseases of the respiratory system (28.4%; 95% CI 24.0-32.8%), endocrine, nutritional and metabolic disorders (26.2%; 95% CI 21.9-30.5%) and diseases of the musculoskeletal system (21.2%; 95% CI 17.5-25.5%).

Ninety five patients (23%; 95% CI 18.9-27.1%) were taking up to two medications on admission. Two hundred and sixty four patients (65%; 95% CI 60.8-69.2%) were taking four or more medications on admission. The most common drugs on admission were drugs affecting the cardiovascular system (69.9%; 95% CI 65.5-74.3%), drugs affecting the central nervous system (44.5%; 95% CI 39.7-49.3%), drugs affecting the endocrine system (27.4%; 95% CI 23.1-31.7%) and drugs affecting the respiratory system (27.1%; 95% CI 22.8-31.4%).

There was no significant difference between females and males in the number of admission diagnoses or in the number of previous diagnoses, but females did tend to be on more medications than males (5.22 vs 4.43; t=2.512, p=0.012). The number of admission diagnoses and the number of previous diagnoses showed a significant trend with age in males (F trend=10.877, p=0.001 and F trend=5.519, p=0.02 respectively) and there was a significant trend in the number of medications taken with age in females (F trend=3.902, p=0.049).

5.4.3 Medication related problems and medication related admissions

Tables 5.2, 5.3 and 5. 4 show the proportion of patients with medication related problems, medication related admissions and preventable medication related admissions, classified by the type of medication problem, drugs involved and the associated outcomes.

One or more medication related problems were identified in fifty seven admissions (14%; 95% CI 10.6-17.4%). The registrar accepted as such, all cases classified by the pharmacist as suffering medication related problems (Table 5.2).

Table 5.2: Medication related problems

Variable		Number	percentage	95% CI lower limit	95% CI upper limit
Medication related problems	Patients affected	57	14.0%	10.6%	17.4%
Strand criteria!	Failure to prescribe	24	5.9%	3.6%	8.2%
	Wrong drug	0	0.0%		
	Under dosage	8	2.0%	0.6%	3.4%
	Over dosage	5	1.2%	0.1%	2.3%
	Adverse reaction	16	3.9%	2.0%	5.8%
	Interaction	4	1.0%	0.04%	2.0%
	Not taken	9	2.2%	0.8%	3.6%
	Inappropriate	1	0.2%		
Collapsed classification	Under treatments	41	10.0%	7.1%	12.9 %
	Adverse reactions	16	3.9%	2.0 %	5.8%
	Over treatments	10	2.4%	0.9%	3.9%
Drug classes Involved$	Cardiovascular	46	11.2%	8.1%	14.3%
	Endocrine	3	0.7%		
	Nervous system	2	0.5 %		
	Musculoskeletal	2	0.5%		
Associated Diagnostic Outcomes$$	Circulatory	31	7.6%	5.0%	10.2%
	Endocrine	8	2.0%	0.6%	3.4%
	Digestive system	6	1.5%	0.3%	2.7%
	NEC	4	1.0%	0.04%	2.0%

! Total number of medication related problems recorded=67

$ Cardiovascular drugs (no. of medication related problems): Cardiac glycoside (8), Anti-arrhythmic (1), Diuretics (10), B blockers (6), ACE inhibitors (12), Nitrates (4), Antihypertensives (1), Anticoagulants (1), Anti-platelet (9), Lipid regulating (4). Endocrine drugs (no. of medication related problems): Oral hypoglycaemics (2), Insulin (1). Drugs affecting the nervous system (no. of medication related problems): Antimanic (1), Anticonvulsant (1). Musculoskelatal drugs (no. of medication related problems): NSAID (2). Other drugs (no. of medication related problems): Broncholdilator (1), Antidiarrhoea (1), Macrolide antibiotic (1), Antiproliferative immunospuressant (1).

$$Circulatory (no. of medication related problems): Angina (6), Myocardial infarction (3), CCF (21), Stroke (5), Arrythmia (3). Endocrine and metabolic (no. of medication related problems): Hyperglycaemia (2), Hypoglycaemia (1), Hypothyroid (1), Hypokalaemia (1),Hyperkalaemia (2), Dehydration (1), Renal impairment (2).Digestive system (no. of medication related problems): GI bleed (7). Other (no. of medication related problems): Anaemia (1), Diarrhoea (1), Confusion (1), Exacerbation COPD (1), Seizure (1), Jaundice (1), Hypotension (4), Collapse (2)

Amongst the fifty seven patients in whom medication related problems were identified, forty nine had one medication problem, seven had two problems and one had four problems. The commonest medication related problem was failure to prescribe a required drug in twenty one patients (5.1%; 95%CI 3.0-7.2%) or an adverse drug reaction to a prescribed drug in sixteen patients (3.9%; 95%CI 2.0-5.8%). These were followed by failure to take a prescribed drug in eight patients (2.0%; 95%CI 0.6-3.4%) and under dosage of an indicated drug in six patients (1.5%; 95%CI 0.3%-2.7%).

Problems with cardiovascular drugs accounted for medication related problems in 46 patients (11%; 95%CI 8.1%-14.3%). Outcomes attributable to medication related problems included cardiovascular events (7.6% 95%CI 5.0-10.2%), events associated with endocrine disease (2.0%; 95%CI 0.6%-3.4%) and events affecting the digestive system (1.5%; 95%CI 0.3-2.7%).

Of the 67 medication related problems recorded, diuretics (15%; 95% CI 10.6%-19.3%), ACE inhibitors (18%; 95% CI 8.8%-27.2%), cardiac glycosides (12%; 95%CI 4.2%-19.8%), anti-platelet agents (13%; 95% CI 4.9%-21.1%), and B blockers (9%; 95%CI 2.1%-15.9%) accounted for the majority. The commonest outcomes associated with the medication related problems detected were cardiac failure (31%; 95%CI 19.9%-42.1%), gastrointestinal bleeding (10.4%; 95%CI 3.1-17.7%), angina pectoris (9.0%; 95%CI 2.1%-15.9%), and stroke (7.5%; 95%CI 1.2%-13.8%).

Twenty six admissions (6.4%; CI 4.0-8.8%) were judged to be medication related and sixteen admissions (3.9%; CI 2.0-5.8%) were judged to have been preventable at the conclusion of panel assessment (Table 5.3). The panel disagreed with the registrar assessment that an admission was due to the medication related problems identified in two cases and in one case the panel disagreed with the registrar that that a confirmed medication related admission was preventable. The commonest medication related problem amongst medication related admissions was an adverse drug reaction to a prescribed drug in twelve patients (2.9%; 95%CI 1.3-4.5%) followed by failure to prescribe an indicated drug in five (1.2%; 95%CI 0.3-2.3%).

Table 5.3: Medication related admissions

Variable		number	percentage	95% CI lower limit	95% CI upper limit
Medication related problems	Patients affected	26	6.4%	4.0%	8.8%
Strand criteria!	Failure to prescribe	4	1.0%	0.04%	2.0%
	Wrong drug	0	0.0%		
	Under dosage	3	0.7%		
	Over dosage	3	0.7%		
	Adverse reaction	12	2.9%	1.3%	4.5%
	Interaction	3	0.7%		
	Not taken	3	0.7%		
	Inappropriate	1	0.2%		
Collapsed classification	Under treatments	10	2.4%	0.9%	3.9%
	Adverse reactions	12	2.9%	1.3 %	4.5%
	Over treatments	7	1.7%	0.9%	3.9%
Drug classes Involved$	Cardiovascular	18	4.4%	2.4%	6.4%
	Endocrine	2	0.5%		
	Nervous system	2	0.5 %		
	Musculoskeletal	2	0.5%		
Associated Diagnostic Outcomes$$	Circulatory	8	2.0%	0.6%.	3.4%
	Endocrine	5	1.2%	0.1%	2.3%
	Digestive system	5	1.2%	0.1%	2.3%
	NEC	4	1.0%	0.04%	2.0%

! Total number of medication related problems recorded=29

$ Cardiovascular drugs (no. of medication related problems): Anti-arrhythmic (1), Diuretics (5), B blockers (3), ACE inhibitors (4), Nitrates (2), Antihypertenives (1), Anti-platelet (5). Endocrine drugs (no. of medication related problems): Oral hypoglycaemics (1), Insulin (1). Drugs affecting the nervous system (no. of medication related problems): Antimanic (1), Anticonvulsant (1). Musculoskelatal drugs (no. of medication related problems): NSAID (2). Other drugs (no. of medication related problems): Macrolide antibiotic (1), Antiproliferative immunosurpressant (1).

$$Circulatory (no. of medication related problems): Myocardial infarction (1), CCF (6), Stroke (2). Endocrine and metabolic (no. of medication related problems): Hyperglycaemia (1), Hypoglycaemia (1), Hypothyroid (1), Hyperkalaemia (1),Dehydration (1). Digestive system (no. of medication related problems): GI bleed (5). Other (no. of medication related problems): Anaemia (1), Confusion (2), Seizure (1), Jaundice (1), Hypotension (3), Collapse (2)

Problems with cardiovascular drugs accounted for medication related admissions in 18 patients (4.4%; 95%CI 2.4-6.4%). The most common outcomes attributable to medication related problems amongst medication related admissions were cardiovascular events (2.0%; 95%CI 0.6-3.4%) followed by events associated with endocrine disease and events affecting the digestive system. There were 29 medication related problems amongst the 26 medication related admissions. Diuretics (17%; 95% CI 3.3%-30.7%), ACE inhibitors (14%; 95% CI 1.4%-26.6%), anti-platelet agents

(17%; 95% CI 3.3%-30.7%), and B blockers (10%; 95%CI 0.9%-20.1%) were the drugs most commonly involved. The associated outcomes were cardiac failure (21%; 95%CI 6.2%-35.8%), and gastrointestinal bleeding (17%; 95%CI 3.3-30.7%).

Table 5.4: Preventable medication related admissions

Variable		number	percentage	95% CI lower limit	95% CI upper limit
Medication related problems	Patients affected	16	3.9%	2.0%	5.8%
Strand criteria	Failure to prescribe	2	0.5%		
	Wrong drug	0	0.0%		
	Under dosage	2	0.5%		
	Over dosage	2	0.5%		
	Adverse reaction	5	1.2%	0.1%	2.3%
	Interaction	2	0.5%		
	Not taken	3	0.7%		
	Inappropriate	1	0.2%		
Collapsed classification	Under treatments	7	1.7%	0.9%	3.9%
	Adverse reactions	5	1.2%	0.1 %	2.3%
	Over treatments	5	1.2%	0.1%	2.3%
Drug classes Involved$	Cardiovascular	11	2.7%	1.1%	4.3%
	Endocrine	2	0.5%		
	Nervous system	1	0.2 %		
	Musculoskeletal	1	0.2%		
Associated Diagnostic Outcomes$$	Circulatory	6	1.5%	0.6%	3.4%
	Endocrine	4	1.0%	0.3%	2.7%
	Digestive system	2	0.5%		
	NEC	1	0.2%		

! Total number of medication related problems recorded=17

$ Cardiovascular drugs (no. of medication related problems): Anti-arrhythmic (1), Diuretics (2), B blockers (3), ACE inhibitors (2), Nitrates (1), Anti-platelet (3). Endocrine drugs (no. of medication related problems): Oral hypoglycaemics (1), Insulin (1). Drugs affecting the nervous system (no. of medication related problems): Anticonvulsant (1). Musculoskelatal drugs (no. of medication related problems): NSAID (1). Other drugs (no. of medication related problems): Antiproliferative immunospuressant (1).

$$Circulatory (no. of medication related problems): Myocardial infarction (1), CCF (3), Stroke (2). Endocrine and metabolic (no. of medication related problems): Hyperglycaemia (1), Hypoglycaemia (1), Hypothyroid (1), Hyperkalaemia (1), Dehydration (1). Digestive system (no. of medication related problems): GI bleed (2). Other (no. of medication related problems): Anaemia (1), Seizure (1), Hypotension (1), Collapse (1).

The commonest medication related problem amongst preventable medication related admissions was an adverse drug reaction to a prescribed drug (Table 5.4). This occurred in five patients (1.2%; 95%CI 0.3-2.3%). Problems with cardiovascular drugs

accounted for preventable medication related admissions in eleven patients (2.7%; 95%CI 1.1-4.3%). The most common outcomes attributable to medication related problems amongst preventable medication related admissions were cardiovascular events (1.5%; 95%CI 0.6-3.4%), followed by events associated with endocrine disease and events affecting the digestive system.

There were 17 medication related problems amongst the 16 preventable medication related admissions. Diuretics (12%; 95% CI 0%-27.4%), ACE inhibitors (12%; 95% CI 0%-27.4%), anti-platelet agents (18%; 95% CI 0%-36.2%), B blockers (18%; 95% CI 0%-36.2%) and hypoglycamic agents (12%; 95% CI 0%-27.4%), were the drugs most commonly involved. The associated outcomes were cardiac failure (18%; 95% CI 0%-36.2%), stroke (12%; 95% CI 0%-27.4%) and gastrointestinal bleeding (12%; 95% CI 0%-27.4%).

5.4.4 Predictors of medication related problems and medication related admissions

Table 5.5 shows rates of medication related problems (MRP), medication related admissions (MRA) and preventable medication related admissions (PMRA) by gender and age.

The rate of medication related admission and the rate of preventable medication related admissions tended to increase with age in females (X^2 trend=4.265, p=0.039 and X^2 trend=5.373, p=0.020 respectively). There was no significant difference between females and males in the rate of medication related problems, medication related admissions or preventable medication related admissions (X^2=0.694, p=0.405; X^2=0.001, p=0.974; X^2=0.285, p=0.594).

Table 5.6 shows rates of medication related problems, medication related admissions and preventable medication related admissions as the number of admission diagnoses, the number of previous diagnoses and the number of admissions drugs changes.

Patients with medication related admissions were likely to have more problems documented at the time of admission (2.15 versus 1.75; t=-2.19, p=0.029) and to be taking more drugs at the time of admission (6.15 vs 4.90; t=-2.111, p=0.035).

Medication related problems increased with the number of admission diagnoses (X^2 trend=4.167, p=0.041), with the number of previous diagnoses (X^2 trend=16.267, p<0.001) and with the number of drugs on admission (X^2 trend=5.523, p=0.019).

Table 5.5: Numbers (percentage) of patients with medication related problems (MRP), medication related admissions (MRA) and preventable medication related admissions (PMRA) by age and gender

Age in years	Sex	Adults (N)	MRP (%)	MRA (%)	PMRA (%)
<=70	Males	23	4 (17%)	3 (13%)	1 (4%)
	Females	27	1 (4%)	1 (4%)	1 (4%)
			X^2=2.585	X^2=1.472	X^2=0.013
			p=0.108	p=0.225	=0.908
>70 to <=75	Males	29	5 (17%)	1 (3%)	1 (3%)
	Females	40	4 (10%)	1 (3%)	0
			X^2=0.777	X^2=0.054	X^2=1.400
			p=0.378	p=0.817	p=0.237
>=75 to<=80	Males	30	3 (10%)	3 (10%)	1 (3%)
	Females	59	9 (15%)	2 (3%)	1 (2%)
			X^2=0.470	X^2=1.639	X^2=0.243
			p=0.493	p=0.200	p=0.622
>80 to <=85	Males	22	2 (9%)	1 (5%)	1 (5%)
	Females	67	13 (19%)	4 (6%)	2 (3%)
			X^2=1.257	X^2=0.063	X^2=0.124
			p=0.262	p=0.801	p=0.725
>=85 to<=90	Males	14	1 (7%)	0	0
	Females	49	8 (16%)	6 (12%)	4 (8%)
			X^2=0.750	X^2=1.895	X^2=1.220
			p=0.382	p=0.169	p=0.269
90 or more	Males	9	0	0	0
	Females	40	7 (18%)	4 (10%)	4 (10%)
			X^2=1.837	X^2=0.980	X^2=0.980
			p=0.175	p=0.322	p=0.322
All Ages	Males	127	15 (12%)	8 (6%)	4 (3%)
	Females	282	42 (15%)	18 (6%)	12 (4%)
			X^2=0.694	X^2=0.001	X^2=0.285
			p=0.405	p=0.974	p=0.594
	p value for age trend in males	127	X^2=2.902 p=0.088	X^2=2.253 p=0.133	X^2=0.494 p=0.482
	p value for age trend in females	282	X^2=2.964 p=0.085	X^2=4.265 **p=0.039**	X^2=5.373 **p=0.020**
	p value for age trend in all	409	X^2=0.569 p=0.451	X^2=0.791 p=0.374	X^2=3.019 p=0.082

Medication related admissions also tended to increase with the number of admission diagnoses and the number of drugs on admission, but only the latter was statistically significant (X^2=4.521, p=0.033). There was no relationship of preventable medication related admissions with the number of admission diagnoses, the number of previous diagnoses or the number of drugs on admission.

Table 5.6: Numbers (percentage) of patients with medication related problems (MRP), medication related admissions (MRA) and preventable medication related admissions (PMRA) in relation to number of admission diagnoses, number of past medical history diagnoses, number of admissions drugs.

Type of problem		Adults (N)	MRP (%)	MRA (%)	PMRA (%)
Number of admissions diagnoses	1	195	21 (10.8%)	10 (5.1%)	7 (3.6%)
	2	134	20 (14.9%)	6 (4.5%)	2 (1.5%)
	3 or more	80	16 (20.0%)	10 (12.5%)	7 (8.8%)
p value for trend with no admission diagnoses			X^2=4.167 **p=0.041**	X^2=3.691 p=0.055	X^2=2.213 p=0.137
Number of past medical history diagnoses	0	20	1 (5.0%)	1 (5.0%)	
	1	49	4 (8.2%)	4 (8.2%)	2 (4.1%)
	2	89	6 (6.7%)	3 (3.4%)	2 (2.2%)
	3	88	9 (10.2%)	5 (5.7%)	4 (4.5%)
	4	65	12 (18.5%)	3 (4.6%)	2 (3.1%)
	5	42	12 (28.6%)	3 (7.1%)	3 (7.1%)
	6or more	56	13 (23.2%)	7 (12.5%)	3 (5.4%)
p value for trend with no past medical history diagnoses			X^2=16.267 **p<0.001**	X^2=1.879 p=0.170	X^2=1.522 p=0.217
Number of admissions drugs	0	19	1 (5.3%)		
	1	29	1 (3.4%)		
	2	47	4 (8.5%)	2 (4.3%)	2 (4.3%)
	3	51	7 (13.7%)	5 (9.8%)	4 (7.8%)
	4	46	6 (13.0%)	2 (4.3%)	
	5	51	7 (13.7%)	2 (3.9%)	2 (3.9%)
	6	42	10 (23.8%)	4 (9.5%)	3 (7.1%)
	7	34	5 (14.7%)	2 (5.9%)	
	8	37	8 (21.6%)	2 (5.4%)	2 (5.4%)
	9or more	53	8 (15.1%)	7 (13.2%)	3 (5.7%)
p value for trend with no of drugs on admission			X^2=5.523 **p=0.019**	X^2=4.521 **p=0.033**	X^2=0.830 p=0.362

When the relationships between demographic and clinical variables (excluding number of admissions diagnoses) and medication related problems, medication related admissions and preventable medication related admissions were explored in logistic regression analysis, the number of previous diagnoses was an independent predictor of medication related problems (ExpB 1.39, 95%CI 1.14-1.70; Wald=10.16, p=0.001). No clinical or demographic variable emerged as independent predictors of medication related admissions and preventable medication related admissions.

5.4.5 Relationships in under treatments, adverse reactions and over treatments subgroups

Tables 5.7, 5.8 and 5.9 present the analyses for medication related problems, medication related admissions and preventable medication related admissions attributable to under treatments, adverse reactions and over treatments respectively.

Medication related problems due to under treatment and medication related admissions due to under treatment were related to number of past medical history diagnoses (X^2 trend=21.24, p<0.001; X^2 trend=6.047, p=0.014).

Medication related problems due to adverse reactions and medication related admissions due to adverse reactions were related to number of admission diagnoses (X^2 trend=4.619, p=0.032; X^2 trend=4.169, p=0.041) and to number of admission drugs (X^2 trend=7.866, p=0.005; X^2 trend=6.241, p=0.012). They were not related to number of past medical history diagnoses. Preventable medication related admissions due to adverse reactions was related to age (X^2 trend=5.024, p=0.025).

Medication related admissions and preventable medication related admissions due to over treatment were associated with number of admission diagnoses (X^2 trend=3.848, p=0.050; X^2 trend=3.949, p=0.047) but medication related problems due to over treatment was not related to any demographic or clinical variable.

Table 5.7: Numbers (percentage) of patients with medication related problems (MRP), medication related admissions (MRA) and preventable medication related admissions (PMRA) attributable to under treatment in relation to number of admission diagnoses, number of past medical history diagnoses, number of admissions drugs.

Type of problem		Adults (N)	Undertreatment MRP (n,%)	Undertreatment MRA (n,%)	Undertreatment PMRA (n,%)
Gender	Male	127	8 (6.3%)	3 (2.4%)	2 (1.6%)
	Female	282	25(8.9%)	6 (2.1%)	5 (1.8%)
Pearson X^2 for 2X2 table			X^2=0.777 p=0.378	X^2=0.022 P=0.881	X^2=0.20 P=0.886
Age	<70yrs	50	2 (4.0%)	2 (4.0%)	1 (2.0%)
	70-<80yrs	69	7 (10.1%)	2 (2.9%)	1 (1.4%)
	80-<85yrs	89	7 (7.9%)	1 (1.1%)	1 (1.1%)
	85-<90yrs	89	10(11.2%)	2 (2.2%)	2 (2.2%)
	90-<95yrs	63	4 (6.3%)	1 (1.6%)	1 (1.6%)
	95yrs or more	49	3 (6.1%)	1 (2.0%)	1 (2.0%)
X^2, p value for trend with age category			X^2=0.003 P=0.960	X^2=0.509 P=0.476	X^2=0.030 P=0.862
Number of admissions diagnoses	1	195	14 (17.2%)	5 (2.6%)	4 (2.1%)
	2	134	12 (9.0%)	2 (1.5%)	1 (0.7%)
	3 or more	80	7 (8.8%)	2 (2.5%)	2 (2.5%)
X^2, p value for trend with no admission diagnoses			X^2=0.288 p=0.592	X^2=0.042 P=0.837	X^2=0.000 P=0.987
Number of past medical history diagnoses	0	20			
	1	49			
	2	89	3 (3.4%)	1 (1.1%)	1 (1.1%)
	3	88	5 (5.7%)	2 (2.3%)	2 (2.3%)
	4	65	7 (10.8%)	1 (1.5%)	1 (1.5%)
	5	42	9 (21.4%)	1 (2.4%)	1 (2.4%)
	6or more	56	9 (16.1%)	4 (7.1%)	2 (3.6%)
X^2, p value for trend with no past medical history diagnoses			X^2=21.24 **P<0.0001**	X^2=6.047 **P=0.014**	X^2=2.306 P=0.129
Number of admissions drugs	0	19	1 (5.3%)		
	1	29	1 (3.4%)		
	2	47	3 (6.4%)	1 (2.1%)	1 (2.1%)
	3	51	4 (7.8%)	2 (3.9%)	2 (3.9%)
	4	46	3 (6.5%)		
	5	51	5 (9.8%)	1 (2.0%)	1 (2.0%)
	6	42	5 (11.9%)	2 (4.8%)	2 (4.8%)
	7	34	2 (5.9%)		
	8	37	6 (16.2%)	1 (2.7%)	1 (2.7%)
	9or more	53	3 (5.7%)	2 (3.8%)	
X^2, p value for trend with no of drugs on admission			X^2=1.078 p=0.299	X^2=0.875 P=0.350	X^2=0.015 p=0.904

Table 5.8: Numbers (percentage) of patients with medication related problems (MRP), medication related admissions (MRA) and preventable medication related admissions (PMRA) attributable to adverse reactions in relation to number of admission diagnoses, number of past medical history diagnoses, number of admissions drugs.

Type of problem		Adults (N)	Adverse reaction **MRP (n,%)**	Adverse reaction **MRA (n,%)**	**Adverse reaction PMRA (n,%)**
Gender	Male	127	5 (3.9%)	3 (2.4%)	1 (0.8%)
	Female	282	11(3.9%)	9 (3.2%)	4 (1.4%)
Pearson X^2 for 2X2 table			X^2=0.000 p=0.986[2]	X^2=0.211 P=0.646	X^2=0.239 P=0.591
Age	<70yrs	50	2 (4.0%)	1 (2.0%)	
	70-<80yrs	69	2 (2.9%)	1 (1.4%)	
	80-<85yrs	89	3 (3.4%)	2 (2.2%)	1 (1.1%)
	85-<90yrs	89	3 (3.4%)	2 (2.2%)	
	90-<95yrs	63	4 (6.3%)	4 (6.3%)	2 (3.2%)
	95yrs or more	49	2 (6.1%)	2 (4.1%)	2 (4.1%)
X^2, p value for trend with age category			X^2=0.329 p=0.566	X^2=1.965 p=0.161	X^2=5.024 **p=0.025**
Number of admissions diagnoses	1	195	4 (2.1%)	3 (1.5%)	4 (2.1%)
	2	134	6 (4.5%)	4 (3.0%)	1 (0.7%)
	3 or more	80	6 (7.5%)	5 (6.3%)	2 (2.5%)
X^2, p value for trend with no admission diagnoses			X^2=4.619 **p=0.032**	X^2=4.169 **p=0.041**	X^2=1.970 p=0.160
Number of past medical history diagnoses	0	20	1 (5.0%)	1 (5.0%)	
	1	49	3 (6.1%)	3 (6.1%)	1 (2.0%)
	2	89	2 (2.2%)	2 (2.2%)	1 (1.1%)
	3	88	1 (1.1%)		
	4	65	3 (4.6%)	3 (3.1%)	1 (1.5%)
	5	42	3 (7.1%)	2 (4.8%)	2 (4.8%)
	6or more	56	3 (5.4%)	2 (3.6%)	
X^2, p value for trend with no past medical history diagnoses			X^2=0.405 p=0.525	X^2=0.033 P=0.857	X^2=0.091 p=0.763
Number of admissions drugs	0	19			
	1	29			
	2	47			
	3	51	1 (2.0%)	1 (2.0%)	1 (2.0%)
	4	46	2 (4.3%)	2 (4.3%)	
	5	51	1 (2.0%)	1 (2.0%)	1 (2.0%)
	6	42	4 (9.5%)	1 (2.4%)	
	7	34	2 (5.9%)	2 (5.9%)	
	8	37	1 (2.7%)		
	9or more	53	5 (9.4%)	5 (9.4%)	3 (5.7%)
X^2, p value for trend with no of drugs on admission			X^2=7.866 **p=0.005**	X^2=6.241 **p=0.012**	X^2=3.267 p=0.071

Table 5.9: Numbers (percentage) of patients with medication related problems (MRP), medication-related admissions (MRA) and preventable medication related admissions (PMRA) attributable to over treatment in relation to number of admission diagnoses, number of past medical history diagnoses, number of admissions drugs.

Type of problem		Adults (N)	Overtreatment MRP (n,%)	Overtreatment MRA (n,%)	Overtreatment PMRA (n,%)
Gender	Male	127	2 (1.6%)	2 (1.6%)	1 (0.8%)
	Female	282	8 (2.8%)	5 (1.8%)	4 (1.4%
Pearson X^2 for 2X2 table			X^2=0.585 p=0.444	X^2=0.020 P=0.886	X^2=0.289 P=0.591
Age	<70yrs	50	1 (2.0%)	1 (2.0%)	1 (2.0%)
	70-<80yrs	69	1 (1.4%)		
	80-<85yrs	89	2 (2.2%)	2 (2.2%)	
	85-<90yrs	89	2 (2.2%)	1 (1.1%)	1 (1.1%)
	90-<95yrs	63	1 (1.6%)	1 (1.6%)	1 (1.6%)
	95yrs or more	49	3 (6.1%)	2 (4.1%)	1 (4.1%)
X^2, p value for trend with age category			X^2=1.215 P=0.270	X^2=0.844 P=0.358	X^2=1.853 P=0.173
Number of admissions diagnoses	1	195	1 (1.5%)	2 (1.0%)	1 (0.5%)
	2	134	3 (2.2%)	1 (0.7%)	1 (0.7%)
	3 or more	80	4 (5.0%)	4 (5.0%)	3 (3.8%)
X^2, p value for trend with no admission diagnoses			X^2=2.504 p=0.114	X^2=3.848 **p=0.050**	X^2=3.949 **p=0.047**
Number of past medical history diagnoses	0	20			
	1	49	1 (2.0%)	1 (2.0%)	1 (2.0%)
	2	89	1 (1.1%)		
	3	88	3 (3.4%)	3 (3.4%)	2 (2.3%)
	4	65	2 (3.1%)		
	5	42	1 (2.4%)	1 (2.4%)	1 (2.4%)
	6or more	56	2 (3.6%)	2 (3.6%)	1 (1.8%)
X^2, p value for trend with no past medical history diagnoses			X^2=0.983 p=0.321	X^2=1.149 p=0.284	X^2=0.319 p=0.572
Number of admissions drugs	0	19			
	1	29			
	2	47	1 (2.1%)	1 (2.1%)	1 (2.1%)
	3	51	2(3.9%)	2 (3.9%)	1 (2.0%)
	4	46	1 (2.2%)		
	5	51	1 (2.0%)		
	6	42	1 (2.4%)	1 (2.4%)	1 (2.4%)
	7	34	1 (2.9)		
	8	37	1 (2.7%)	1 (2.7%)	1 (2.7%)
	9or more	53	2 (3.8%)	2 (3.8%)	1 (1.9%)
X^2, p value for trend with no of drugs on admission			X^2=0.824 p=0.364	X^2=0.757 p=0.384	X^2=0.407 p=0.523

In logistic regression analysis, past medical history diagnoses was an independent predictor of medication related problems due to under treatment (ExpB 1.92, 95%CI 1.46-2.54; Wald=21.28, p<0.0001) and medication related admissions due to under treatment (ExpB 1.82, 95%CI 1.11-3.0; Wald=5.53, p=0.019) in logistic regression.

The number of admissions drugs was an independent predictor of medication related problems due to adverse reactions, (ExpB 1.45, 95%CI 1.13-1.87; Wald=8.62, p=0.001), medication related admissions due to adverse reactions (ExpB 1.57, 95%CI 1.18-2.10; Wald=9.40, p=0.002) and preventable medication related admissions due to adverse reactions (ExpB 1.60, 95%CI 1.02-2.50; Wald=4.24, p=0.04). In addition, number of previous diagnoses was significantly related to medication related admissions (ExpB 0.66, 95%CI 0.44 -1.00; Wald=3.85, p=0.05) and age group was significantly related to preventable medication related admissions (ExpB 2.37, 95%CI 1.08-5.22; Wald=4.61, p=0.032).

None of the clinical or demographic variables was related to medication related problems, medication related admissions and preventable medication related admissions due to over use of medications.

5.4.5 Impact of medication related admissions

Data was available on length of stay for 322 patients in the study sample. Medication related admissions accounted for 7.4% of total bed days (95CI 7.16-7.64%) and preventable medication related admissions accounted for 6.7% of total bed days (95%CI 6.06-7.34%). None of the medication related admissions died.

There was no relationship between any of the demographic or clinical variables measured and the length of hospital stay. Patients with medication related problems and preventable medication related problems had longer stays than other patients the opposite was the case for patients with medication related problems (they had shorter lengths of stay than patients without medication related problems). None of the differences were statistically significant. Length of stay data was skew to the left on account of a small number of patients with very long lengths of stay. The data was

reanalysed using logarithmic transformation of length of stay as the dependent variable, but no associations with clinic or demographic data, with the existence of medication related problems, or with medical related admission emerged.

5.5 DISCUSSION

5.5.1 Summary of main findings

In this study 14% of older people admitted to the medical admissions unit of an acute hospital had medication related problems. In 6% of patients these problems contributed to the admission and about 4% of admissions were judged preventable. Under-treatments, adverse reactions and over treatments were more equally represented amongst patients in whom admissions were judged preventable. Cardiovascular drugs were the group most often involved and cardiac failure or gastro-intestinal bleeding were the outcomes that most often accounted for the admission. The rate of medication related problems increased with the number of admission diagnoses, past medical history diagnoses and admission drugs. In logistic regression analyses, the number of past medical history diagnoses was an independent predictor of medication related problems and medication related admissions attributable to under treatment. The number of admissions drugs was an independent predictor of medication related problems, medication related admissions attributable to adverse reactions.

5.5.2 Strengths and weaknesses of the study

This was a small study based on a three month data collection period in the medical admissions unit of a single district general hospital. Men were slightly underrepresented in the study population compared to the patients appearing on the hospital database during the same period. There was an under enumeration of approximately fifteen percent, which is attributed to exclusion of re-admissions, and losses during weekends and a short leave period.

The short duration and the committed research team did nevertheless enable careful quality control of the occurrence screening process. Published criteria were used for identifying medication related problems, for identifying medication related admissions and preventability. A study pharmacist and a specialist registrar worked closely together to bring consistency and reliability to the process. Final decisions on attribution of admissions to medication related problems and on preventability were made by an expert group that included a senior pharmacist, consultant geriatrician and a general practitioner.

The inter-rater reliability for assessing whether an adverse outcome is due to a drug using definite, probable, possible and doubtful categories has been reported as poor to moderate, with Kappa of 0.21-0.40, but increasing to Kappa 0.69-0.86 when an explicit scoring system is used (Naranjo *et al.*, 1980). In this study, the accuracy of pharmacist screening following a period of training was Kappa 0.78 in formal testing.

The reliability of the assessment of attribution and preventability was not tested. However, in a recent study using design and assessment criteria similar to ours, pairs of assessors demonstrated high interrater reliability assessments for drug related cause, contribution to admission and preventability with Kappa of 0.68-0.81 (Howard *et al*, 2003). Submission of materials to an expert group can further improve the reliability of assessments through consensus decision making with reliability increasing with the number of participants up to four (Taxis *et al.*, 2002).

5.5.3 Implications for primary care

The level of prescribing in general practice settings reached 617 million prescriptions per year in 2001, representing 85% of all prescriptions (Department of Health, 2003). Over half of the adverse events reported in a large incident monitoring study in general practice were medication related and almost 80% of these were considered preventable (Bhasale *et al.*, 1998). Errors in medication management in primary care are an important cause of morbidity and mortality (Avery *et al.*, 2002).

Research indicates that patients show lack of understanding of their medication regime and the reasons different drugs are being prescribed (Ross, 1998). Relative isolation from other professional influences and the difficulty of maintaining expertise across a wide range of therapeutic areas may make prescribing in general practice problematic (Iliffe, 2000). The risk of potentially inappropriate drug combinations can increase with the number of physicians involved (Tamblyn *et al.*, 1996). Failing of effective teamwork may affect prescribing rationality (Ibanez *et al.*, 1994, Ross, 1988) and lack of systems to check or monitor medications can lead to medications being taken incorrectly, with associated risks and unnecessary morbidity (Lesar *et al.*, 1997; Leape *et al.*, 1995; Solberg *et al.*, 1997). Overall however there is much more to be done to understand quality and safety issues in primary care and how they impact on patient outcomes.

5.5.4 Implications for research to follow

The tenet of this thesis is that investigation of accidents in primary care settings can lead to much better understanding of general practice as an organisational form. Quantitative research is typically associated with the process of statistical estimation or hypothesis testing based on comparisons. The main purpose of this type of research is to characterise, describe or compare people or groups in populations following measurements in a sample. The process is inference and the application of statistical theory enables this to be done with some precision (Rothman, 1986). The study described in this chapter shows the scale of the problem of medication related admissions in older people in north London and characterises the population groups that are affected. The data provided illustrates the types of problems that occur in the medication management process, the drugs involved and their impact on patients. This kind of study design is limited in the degree to which it can clarify why problems occur. For this purpose, research using qualitative method is likely to be most helpful (Strauss and Corbin, 1998).

In the next chapter a linked study is described that is directed towards identifying the kinds of factors that operate alone and together to compromise the medication management process. This work complements and extends what is understood from the

study in this chapter and should feed more directly into the development and implementation of new approaches to reducing medication related problems and their consequences for older patients.

6. CIRCUMSTANCES SURROUNDING PREVENTABLE MEDICATION RELATED ADMISSIONS

6.1 INTRODUCTION

Adverse reactions to medicines are common in older people and some medicines that could reduce illness are not always prescribed for patients who would benefit (Department of Health, 2001a; Department of Health, 2001b). Careful prescribing, monitoring and review is necessary because the potency of the drugs involved and the effects of age related changes in drug handling make older people more susceptible to drug effects (Morris *et al.*, 2002). One of the manifestations of poor medication management in this group can be medication related problems that can be associated with outcomes sufficiently serious to require hospital admission.

The study population for the research described in this chapter comprises preventable medication related admissions identified in an occurrence screening study in a district general hospital. In this study, described in Chapter 5, 14% of patients aged sixty five years and older and admitted to hospital had medication related problems, 6% were admitted due to medication related problems and 4% of admissions were with potentially preventable medication related problems. The rate of medication related problems increased with the number of admission diagnoses, past medical history diagnoses and admission drugs. The commonest type of medication related problem was failure to prescribe a required drug, and cardiovascular drugs were the group most often involved.

Research into causes of medication problems has tended to focus on identifying and classifying errors in the medication management process. Typically these will be grouped as associated with prescribing, dispensing and administration (Avery *et al.*, 2002; Howard *et al.*, 2003). Recent years have seen important changes in the theory of organisational accidents. In particular, human factors psychologists emphasise the importance of distinguishing between so called "active failures", the acts of omission or

commission associated with adverse outcomes and "latent failures" such as communication difficulties, system failures and problems with management or organisational policy that provide the setting in which errors or "active failures" are likely to occur (Reason, 1997).

There is also a broad literature in social sciences on professional judgement, interprofessional working and organisational behaviour that can bring additional theoretic insights into the workings of organisations and the implications for delivery of care (Davies, 2003). Analysis of the causes of incidents at this level can take the investigator beyond the specific issue of medication management problems and bring understanding that can fuel organisational improvement with more generic consequences for quality and safety in healthcare delivery (Vincent *et al.*, 1999).

6.2 METHOD

The aim of this part of the research is to investigate the factors that contribute to medication management problems in older people and to explore the fundamental structural factors that affect quality and safety in primary care.

The research design is a critical incident approach (Bradley, 1992b) adopted to bring focus to particular situations where things have gone wrong. Cases for investigation were identified in the occurrence screening study described in Chapter 5, and a case series was assembled and analysed (Yin, 1989). The investigation of individual cases and the analysis of the case studies, derive crucially from the accident investigation approach that has been identified and developed through the work of this thesis. The structured analysis derived from the investigative approach (Vincent *et al.*, 1998) was applied and complemented by reanalysis using an open coding approach with constant comparison to identify and illustrate higher level contextual themes (Strauss and Corbin, 1998).

The hospital ethics committee and relevant local ethics committees granted approval for the research.

6.2.1 Study setting

The study was conducted in a north London health community, specifically a district hospital and adjoining primary care trusts. The population served was characterised by relatively high levels of deprivation, large variations between wards, and higher proportions of young adults than in England and Wales as a whole. Eighty two percent of admissions originated from two primary care trusts, each served by about forty general practices of which half were small, or single handed practices. District nursing teams were based at larger health centres and cover designated localities. There was a network of community pharmacists, the majority of them in private ownership.

6.2.2 Study sample

Detail of the occurrence screening research from which the study sample is derived appears in Chapter 5. A hospital pharmacist based on the medical admissions ward of the hospital reviewed the clinical notes, referral letters and drug charts of patients of sixty five years or more. Possible medication related problems were classified against definitions covering under use, misuse and overuse of medications (Strand, 1990). A specialist registrar assembled information from medical records and test results, reviewed the cases and took decisions on attribution of admissions to medication related problems (Hallas *et al.*, 1990). An interim decision was taken on likely preventability. Available information was then presented to a panel, comprising a consultant geriatrician, a senior pharmacist and a general practitioner who were responsible for final decisions on attribution and preventability by consensus (Naranjo, 1981; Stanton *et al.*, 1990; Dartnell *et al.*, 2002). Patients with preventable medication related problems were the study population for this research.

6.2.3 Recruitment of patients

All patients admitted with preventable medication related problems were asked if they would allow us to conduct research into medication management issues surrounding their admission. Patients were told that this would involve interviews with health and social care staff involved in their care and a detailed information sheet was provided describing the background and purpose of the study (Appendix 12). If the patient consented the registrar conducted an interview using a structured questionnaire. This was designed to ascertain the patient's social situation, the rationale for their prescribed medicines, the arrangements for collection of prescriptions, and for dispensing and administration of medications. Finally, it asked them to explain whether they had any difficulties at any of these stages of medication management (Appendix 13).

6.2.4 Recruitment of informants

It was anticipated that general practitioners would be central to the process of creating case chronologies and identifying informants and no attempt was made to proceed with cases where general practitioners had decided they did not wish to participate in investigations. A case synopsis was prepared, giving details of the patient, their medical history and social circumstances, together with a brief description of the admission diagnoses, past medical history and medication taken at the time of admission. This was appended to an information sheet describing the background and purpose of the study, the non-judgmental stance, the confidential nature of the enquiry and safeguards to assure anonymity, and sent to the patient's general practitioner with an invitation to participate (Appendix 14, 15). A reply paid envelope was provided for an opt out option. General practitioners not opting out were contacted by telephone to arrange an opportunity for a practice based interview.

Contact details of additional informants were ascertained from general practitioners. Similar methods were used to those used initially in recruiting general practitioners. In two cases senior nurse managers were also approached for permission to interview junior members of the district nursing team who had already consented to act as informants.

6.2.5 Interviewer training

The interviewer was a psychology graduate with experience in qualitative interviews. She had previously worked at the Clinical Safety Unit at University College London and was familiar with a human factors framework for the investigation and analysis of clinical incidents in healthcare (Vincent et al., 1998). Additional insights were gained from the pilot work described in Chapter 4, and the primary care guidance that was generated in the course of this research. Cases of preventable medication related admissions were identified during the development of the occurrence screening instruments described in Chapter 5. Two cases were investigated by the interviewer using the methods described, in the run up to the definitive study. This allowed further discussion and review of the interview methods that were to be employed.

6.2.6 Interview procedure

The interviewer discussed each case with the principal investigator prior to interviews. They jointly agreed the time period prior to admission that would be explored and the kinds of issues that might be pertinent to the case. Guidelines and protocols that were relevant to the use of specific drugs and medical conditions were reviewed and discussed before interviews took place. A letter confirming arrangements for interview was sent with a request that informants familiarise themselves with the index case prior to the interview. Interviews were conducted at a time and place convenient to the informant and usually took about an hour.

The interviewer started the interview by explaining the background and purpose of the study and the form that the interview would take. The interviewer emphasised that the enquiry was confidential and non-judgemental. She explained that time would be devoted to establishing the chronology of events and then to eliciting informant's views on why problems with medication management had occurred. The interviewer used question probes to ensure that informants considered possible problems in prescribing, monitoring and administration in relation to the chronology obtained and to elucidate not only "how" problems might have occurred, but also "why" with reference to the human factors framework.

Each of these problems is designated a "care management problem" and indicates acts or admissions in the delivery of care to the patient that might have contributed to the incident under investigation. The next step is to specify the conditions associated with the care management problem with reference to the framework embedded in the investigative process. This involves consideration of the extent to which factors related to the patient, staff, systems, teams, work environment, organisation and management and institutional context might have been relevant and acknowledging that several factors at different levels in the framework might be relevant to any care management problem (see Appendix 8 for details) .

At the conclusion of every interview the interviewer summarised what she thought had been learned about the direct and contributory causes relevant to the outcome in the case. A summary was made of the informant's views on the contribution of patient, staff, system, team, work environment, organisation and management and institutional context to the outcome.

When multiple informants contributed to case studies, information was sought without sharing material between informants. Interviews were audio taped for later transcription. When informants' declined consent for audio records, notes were taken and written up immediately. The interviewer also kept a reflexive diary, noting issues and considerations that emerged and adding comments to the subsequent transcripts.

6.2.7 Structured analysis against human factors framework

Case chronologies were prepared using information from all informants involved in a particular case. Where inconsistencies were detected, transcripts were rechecked. Patient pathways and accounts of communications between individuals were reconstructed from interview material. Informants' accounts of systems and policies and how they operated were documented. Genuine inconsistencies between accounts were written into case reports with a reference to the transcript in the respective report. Where inconsistencies might have arisen from interviewer interpretation, a note was made to check back with the original informant.

Care management problems raised by informants were identified and listed. For each care management problem, transcripts were reviewed again to identify possible contributory factors. Contributory factors were then organised against the causal factor classification described by (Vincent *et al.*, 1998) which informed the structure of our interviews and which were used subsequently as our analytic framework. This is described in detail and presented with an example in Appendix 8.

The interviewer and the principal investigator carried out the analytic process independently and compiled a draft report jointly through discussion and iteration. Reports comprised a section on the chronology of events and an account of various care management problems and associated contributory factors. Case reports were circulated amongst informants who were asked to provide feedback on the accuracy of the report, and the presentation as a no-blame anonymous investigation. Specific questions were addressed to informants where clarification was needed to finalise the report. Finally, informants were asked to provide signed consent for the release of reports.

6.2.8 Inductive analysis of transcripts

The transcriptions of the sets of interviews were subsequently reanalysed using an open coding and constant comparison method. The approach makes no assumptions about the structure of the data, acknowledges the complexity and variability in the data, but seeks to identify patterns that can test or develop theory (Strauss and Corbin, 1998). Interviews were loaded onto a software programme designed to support the coding and data arrays that characterise this mode of analysis (QSR Nudist Rev 4: Qualitative Solutions and Research Pty Ltd, Melbourne Australia, 1997).

Interviews were read several times and segments of text relating to the emergence of medication related problems, their relations and contexts were coded and logged. This analytic framework was developed through iteration into topics and themes. Topics, themes and interpretations were checked against findings in other case reports to evaluate their plausibility and consistency.

The process of coding and recoding led to the generation of a tree structure for categories in which general practice as an organisational form, the delivery of care in the community and working with hospitals comprised the major branches.

Subcategories within the general practice grouping included changing relationships between general practitioners and other healthcare staff, inadequate systems development and hazards associated with policy implementation. Subcategories within the care in the community grouping included home visits, themes relating to nursing roles and boundaries, themes relating to joint working and lastly pharmacy care. Finally, subcategories within the working with hospitals group included shared care, specialisation and communication across the interface. These categories and subcategories comprise the framework for presentation of relevant narrative in the results section below.

Relational properties of particular scenarios were studied to build explanatory frameworks and searches of text were made in order to secure the evidence base for particular propositions. Negative instances and contradictory findings were acknowledged and integrated into the fabric of explanatory narratives. These approaches underpin the descriptions of diversity within the subcategories and explanations of certain behaviours. For example, three models of shared care are described in the section on working with hospitals. Open coding yielded a number of blocks of text that described issues relating to shared care. Shared care of itself was assumed to be a straightforward concept until further systematic search yielded data demonstrating that three models for shared care, while further examination yielded text suggesting that, for some informants, shared care was a negotiated concept, that could be problematic if based assumptions of general practitioner or consultant acting alone.

The software allows sections of text to be marked, so that relevant text can be retrieved as evidence for assertions that are made in theory development. In order to enhance the validity of the process of analysis an experienced qualitative researcher read and coded a selection of interviews. Codes, themes and interpretations were discussed throughout the process of creating explanatory narratives to ensure the approach was robust.

6.3 RESULTS

Amongst four hundred and nine medical admissions to a district general hospital sixteen patients were identified with medication related admissions judged to be preventable. Ten patients gave consent for research to be conducted into the circumstances surrounding their medication related problems. The demographic and clinical characteristics of these patients are summarised in Figure 6.1.

Figure 6.1. Patients consenting to investigation into circumstances of medication management problems.

Patient *ID*	**Description**	**GP consent**
F/94yrs *110*	*Medical conditions*: Coronary heart disease, hypothyroidism, sciatica, gout, constipation *Index admission*: Presyncope secondary to medication	No time, not interested
F/89yrs *133*	*Medical conditions*: Rheumatoid arthritis, hypertension *Index admission*: Pancytopenia secondary to methotrexate	Yes
M/70yrs *139*	*Medical conditions*: Partial gastrectomy, prostate cancer, hypertension *Index admission*: Gastrointestinal bleeding secondary to taking self prescribed aspirin	Yes
M/79yrs *202*	*Medical conditions*: Myocardial infarction, prostate cancer, glaucoma, cataract *Index admission*: Postural hypotension, resolved on reducing anti-hypertensives	Too busy
M/92yrs *216*	*Medical conditions*: Coronary heart disease, peripheral vascular disease, chronic obstructive pulmonary disease, ++ *Index admission*: Myocardial infarction and exacerbation of chronic obstructive pulmonary disease, inadequate medications	Concerns about the study
F/70yrs *295*	*Medical conditions*: Diabetic, hypertension, chronic obstructive pulmonary disease, angina *Index admission*: Collapse following uncontrolled blood sugar levels	Yes
F/89yrs *355*	*Medical conditions*: Glaucoma, osteoarthritis, constipation, pacemaker for sick sinus syndrome *Index admission*: GI bleed, secondary to aspirin and clopidogrel	Yes
F/92yrs *389*	*Medical conditions*: Known diabetic *Index admission*: Recurrent hypoglycaemic episodes prior to admission	Yes
F/93yrs *392*	*Medical conditions*: Heart failure, atrial fibrillation, chronic obstructive pulmonary disease *Index admission*: Renal failure, and hypothyroidism, secondary to medication	Yes
F/79yrs *394*	*Medical conditions*: Diabetic, congestive cardiac failure, coronary hart disease, urinary incontinence, hypertension, ++ *Index admission*: Exacerbation of congestive cardiac failure and not taking prescribed diuretics	Yes

Patients' general practitioners agreed to participate in seven cases. Two general practitioners cited insufficient time or lack of interest as reasons for non participation. A third expressed a view that the work was about performance rather than a vehicle for learning and implied that research was a waste of time. Participating general practitioners identified additional informants during the interview process. All additional informants agreed to participate, with the exception of one pharmacist who indicated they were not interested. Two general practitioners and a hospital specialist nurse refused permission for an audio-taped record to be made.

Nineteen interviews were conducted in total, but two participating hospital consultants subsequently asked that their interviews and those of a hospital based specialist nurse be excluded on grounds of sensitivity relating to service issues. As such the analysis draws only on accounts of informants in primary care settings, drawing on interviews with seven general practitioners, four district nurses, one specialist nurse, and four pharmacists.

Figure 6.2. Support for medication management from patient interviews

Patient ID	Patient residence	First language	Medication prescribed by	Prescription collected by	Problems encountered when taking medication
F/89yrs *133*	Alone	English	GP and Consultant	Friend	Problems removing medicines from container Difficulty in reading labels
M/70yrs *139*	Alone	English	GP	Patient	No reported problems
F/70yrs *295*	Alone	English	GP	Relative	Forgetting to take medication
F/89yrs *355*	Alone	English	GP	Relative	No reported problems
F/92 yrs *389*	Care home	English	GP	Pharmacy service	Medication given by district nursing
F/93yrs *392*	Alone	English	GP and Consultant	Relative	Forgetting to take medication Dosette box used
F/79yrs *394*	With spouse	Greek	GP and Consultant	Relative	No reported problems

All patients except one were women, and the average age was eighty three years (range 70 – 93 years). Five of the patients lived alone, one with a spouse and one in a care home. Only one patient collected their own prescriptions, two patients said that they tended to forget to take their medications (one used a dosette box), one had practical difficulties with self administration and district nurses administered medication to a third patient (Figure 6. 2).

6.4 ANALYSIS USING THE HUMAN FACTORS FRAMEWORK

Three care management problems were identified in four case studies and four care management problems in three case studies. Care management problems included combinations of failure to elicit or record relevant information (4); questionable prescribing decisions (2); failure to follow up after medication changes (4); failure to monitor a patient prescribed regular medications (5); failure to act on abnormal findings (5); failure to diagnose a problem (1); and delayed response in assessing a patient (3).

The proximal determinants of adverse outcomes were underpinned by contributory factors operating across the human factors framework (Figure 6.3). In this section I describe the patterns of contributing factors that relate to the seven types of care management problems identified.

Figure 6.3. Care management problems and underlying factors

Case description and care management problems	Factor					
	Patient	Staff	Task	Team	Work environment	Organisational management
Case 133: Pancytopenia in patient taking methotrexate						
133-A1 Failure to arrange monitoring of patient taking methotrexate	✗	✗	✓	✓	✓	✓
133-A2 Failure to call patient for hospital based monitoring following general practitioner's request	✗	✓	✓	✗	✗	✓

Case description and care management problems	Factor					
	Patient	Staff	Task	Team	Work environment	Organisational management
133-A3 District nurses dropped patient from case load after taking blood on two occasions	✓	×	✓	✓	✓	✓
133-A4 Failure to act on abnormal blood tests from attendance at Accident and Emergency Department	✓	×	✓	×	×	×
Case 139: Gastrointestinal bleeding secondary to taking self prescribed aspirin						
139 – A1 Failure to record (over the counter) aspirin use on the medication record	✓	✓	✓	✓	✓	✓
139 – A2 Questionable decision to recommend aspirin	✓	✓	✓	×	×	×
139 – A3 Failure to elicit a medication history before prescribing rofecoxib	✓	✓	✓	✓	✓	×
Case 295:Collapse following uncontrolled high blood sugar levels						
295 – A1 Failure of general practitioner to follow up after medication changes	✓	✓	✓	✓	✓	✓
295 – A2 Delay in assessment by podiatrist	✓	✓	✓	×	×	✓
295 – A3 Delay in assessment by optometrist	✓	×	✓	✓	✓	✓
295 – A4 Failure of practice nurse to act on an abnormal clinical finding	✓	✓	✓	✓	✓	✓
Case 355: Gastrointestinal bleeding, secondary to aspirin and clopidogrel						
355 – A1 Failure to monitor long term use of non steroidal anti-inflammatory drugs	✓	✓	✓	×	×	×
355 – A2 Questionable co-prescibing of diclofenac, aspirin and clopidogrel	✓	✓	✓	✓	×	✓
355 – A3 Failure to follow up after initiation of new medications	×	✓	✓	×	×	✓
Case 389: Recurrent hypoglycamic episodes preceding admission						
389 – A1 Failure of the primary care team to follow up after medication changes	✓	✓	✓	✓	✓	✓
389 – A2 Delay in responding when patient suffered hypoglycaemic attacks	✓	✓	✓	✓	✓	✓
389 – A3 Failure of health and social care staff to diagnose an injury after a fall	✓	×	✓	✓	✓	×
Case 392: Renal failure and hypothyroidism secondary to medication						
392 – A1 Failure to elicit the results of a blood test done in hospital	×	✓	×	✓	×	✓
392 – A2 Failure to elicit relevant information on medications taken	✓	×	✓	✓	×	×
392 – A3 Failure to act on abnormal results by hospital staff	×	×	✓	✓	✓	×
392 – A4 Failure to act on abnormal results by general practitioner	✓	×	✓	✓	✓	×

Case description and care management problems	Factor					
	Patient	Staff	Task	Team	Work environment	Organisational management
Case 394: Exacerbation of congestive cardiac failure and not complying with diuretics						
394 – A1 Failure of general practitioner to follow up after medication changes	✓	✓	✓	✓	✓	✓
394 – A2 Failure of pharmacist to monitor the patient's use of medications	✓	✗	✓	✓	✗	✗
394 – A3 Failure of district nurses to act on their findings of continence problems	✓	✗	✓	✓	✓	✓

6.4.1 Failure to elicit or record relevant information

Two examples derived from one case study and two from another case study:

In one case study (Case 139) an elderly man with hypertension and a history of a gastric ulcer was taking aspirin bought over the counter for primary prevention of heart disease, apparently on the recommendation of a previous general practitioner. This recommendation was not recorded in the patient's notes, nor did a second general practitioner ask whether the patient was taking any over the counter drugs before prescribing rofecoxib. A pharmacist indicated that it was usual to check for contraindications when a new drug is dispensed. The general practitioner and the pharmacist indicated that their work environments could lead to slips or place constraints on their interactions with patients. The general practitioner implied that a centrally driven policy to improve access for patients had detrimental effects on the conduct of the consultation by increasing interruptions.

In the other case study (Case 392) blood tests relevant to the initiation of new drugs were done during a hospital admission, but the results were not available at the time of discharge and never made available to the general practitioner. Factors around staffing pressures in the hospital setting were thought to be contributory. In the same case study there was a hospital outpatient visit, but the registrar had no information on the drugs the patient was taking. Patient factors were relevant as the outpatient letter

flagged the need to bring all medications. Subsequent attempts to clarify the situation were unsuccessful, as the general practitioner did not respond to a written request for prescribing information.

6.4.2 Questionable prescribing decisions

Interestingly both of these care management problems related to questionable prescribing of aspirin and/or non-steroidal inflammatory drugs:

The first example is described in the preceding section (Case 139). A man with hypertension had discussed primary prevention of heart disease with a general practitioner and had been recommended daily aspirin, even though he had had a gastric ulcer in the past. In the second example (Case 355), a patient taking diclofenac for joint problems attended a hospital outpatient department and was advised to take aspirin and then aspirin and clopidogrel for atrial flutter. The prescription was issued by the general practitioner in addition to the diclofenac and without considering gastro-protection; the patient suffered with gastrointestinal bleeding.

6.4.3 Failure to follow up after medication changes

This care management problem was seen in three case studies (Cases 295, 394 and 389 respectively). One related to a change in insulin dose, one to a change in diuretics and one to a change in dose of oral hypoglycaemic drugs.

The first example (Case 295) involved a patient with brittle diabetes, who was demented and lived in a care home. District nurses accepted responsibility for administering the patient's insulin, but assuring appropriate dietary intake was difficult and the use of a more complex insulin regime not feasible in the care home setting, so the patient's diabetes was never well controlled. In the second example (Case 394), a series of general of practitioners made house calls on a patient. One instituted the medication change but there was poor continuity of care on account of the rotation system for visits and inadequate record keeping. In the third example (Case 389) the patient considered themselves housebound, medication changes were made on the basis

of telephone advice and there were difficulties around arranging systematic follow up of the patient in their own home.

6.4.4 Failure to monitor a patient prescribed regular medications

In three case studies (Case 133, 355, 394) monitoring of regular medications might have assured patient safety, but this did not occur.

In the first case (Case 133) there were failures on the part of general practitioner, hospital and district nurses to monitor a patient taking methotrexate. The hospital asked the general practitioner to arrange monitoring in the community. He sent requests to the district nursing service for blood samples to be taken and called the hospital to ask that the patient be monitored at the clinic, in the knowledge that the district nurses would not visit on a regular basis. The hospital never recalled the patient and the district nurse dropped the patient from the caseload after two blood tests. The general practitioner never confirmed that the hospital had initiated the monitoring following his request.

Another case (Case 355) was a patient taking non steroidal anti-inflammatory drugs for many years. There was never any review of this prescription, despite risks of bleeding in older patients and of renal failure with longstanding use. Subsequently aspirin and then clopidogrel were added to the repeat prescription without considering the cumulative risk of gastro intestinal bleeding. The third case was a patient with congestive cardiac failure and poor diuretic use (Case 394). The pharmacist held records for the patient, but these were incomplete. The husband collected the medications, so the pharmacist was unable to counsel the patient. He thought that he was not the only pharmacy that was used and that use of other pharmacies for prescriptions could explain the gaps in prescriptions issued.

6.4.5 Failure to act on abnormal findings

Two of these care management problems involved nurses (Case 295, 394) and three (two in the same case study) involved doctors (Case 392, 133). The omissions were generally compounded by communication and work environment factors.

In Case 295, a practice nurse had taken the unusual step of conducting a patient's annual diabetic check in their home. She had found a peripheral pulse to be absent when examining the patient's feet and wrote this in the notes when she returned to the surgery. There was no verbal communication with the general practitioner and no action was taken. The index admission was with poor diabetic control and the patient was fount to have sepsis in the affected foot. In Case 394 a number of general practitioners had visited the patient's home and adjusted medications to improve control of the patient's heart failure. One of the district nurses was visiting the same patient to help manage continence problems. It subsequently became clear that the patient was not taking her diuretics because of continence problems, but this went unnoticed as the general practitioner was not aware of the continence visits and the significance of the medications to the patient's problem was not fully appreciated.

In Case 392 a hospital doctor and the general practitioner had failed to act on an abnormal result. At the hospital, the result had come to the consultant's attention, but no direct action was taken. The consultant noted the abnormal result on an outpatient letter to the general practitioner. The general practitioner saw this, but took no action. The general practitioner argued he wasn't sure of the most appropriate action and assumed that the hospital would sort things out through a further outpatient appointment. In Case 133, a blood test was taken at an Accident and Emergency visit (a full blood count in a patient with haemoptysis). The discharge letter noted that this was abnormal (a low haemoglobin and platelet count), but the significance of this was not appreciated. The patient was subsequently admitted with pancytopenia related to the methotrexate she was taking.

6.4.6 Failure to diagnose a problem

There was one example of a missed diagnosis (Case 389). A patient had fallen at a care home. The staff called the general practitioner for a visit. The staff indicated that the the patient fell on her arm, but that the patient was using it normally. The general practitioner was reassured and decided not to visit. The next day the staff rang again to

say there was extensive bruising. The general practitioner sent the patient directly to Accident and Emergency and a fracture was diagnosed.

6.4.7 Delayed response in assessing a patient

There were three examples of this care management problem, two in one case study (Case 295) and one in another case study (Case 389).

In the first case study (Case 295) delays in assessment of a diabetic patient centred around the fact that the patient considered themselves housebound. The general practitioner implied this was as much a social as a medical phenomenon and left it to the patient's daughter to make arrangements for domiciliary optometry and chiropody. There was a limited capacity to conduct such visits and the approach was not per protocol for diabetic annual reviews. It was some time after the review date that the optometrist visited and the patient developed complications affecting one of her feet while awaiting chiropody. In Case 389, there were delays in responding when a patient suffered hypoglycaemic attacks. The patient lived in a care home and the staff had been taught how to recognise hypoglycaemia and what to do. The district nurse and the diabetic specialist nurse were the main staff involved in the medical care of the patient. The general practitioner typically got involved only after the district nurse had been in to assess the situation, so introducing further delay.

6.5 OPEN CODING AND CONSTANT COMPARISON

The substantive detail emerging from transcripts using a grounded analysis was classified within three broad contextual topics: general practice as an organisational form in transition, providing care in the community and working with hospitals. The contextual topics and the thematic contents relating to them are described below to illustrate the complexity and dynamic nature of the healthcare environment at the time of the study.

6.5.1 General practice in transition

The sector is described as "in transition" as there was a strong sense that general practice has shifted away from historic norms, but without as yet having arrived at its destination. Key themes emerging from informants' accounts included changing relationships, inadequate system development and unanticipated consequences of new policies.

6.5.1.1 Changing relationships Many comments and assumptions made in case studies reflected core values of general practice. A holistic approach to care, consideration of patient's social circumstances and pragmatism in the face of complex situations was often demonstrated. However, changing staffing patterns and ways of working signal the need for adaptations to be made to assure only positive consequences arise from new working configurations:

There appears to have been some erosion of the concept of the "personal doctor" over recent years with increasing staff mobility and part time working amongst general practitioners.

"OK, I'm just looking at the computer record here. I see I saw her after the admission. It looks like most of the contact before the admissions was with my colleague... but not exclusively so. I see she's seen ... before, on a couple of occasions." (General Practitioner, Case 355, 6, *verbatim*)

All practices in the study employed practice nurses who assisted with chronic disease monitoring and they were responsible for at least some of the follow up of such patients.

" ... explained that patients with hypertension were monitored on a regular basis every three to six months. Monitoring was done either by the practice nurse or the doctor as appropriate." (General practitioner, Case 139, 46, *interviewer's notes*)

District nurses and specialist nurses as well as general practitioners were involved in providing care to patients in their own home and general practitioners were not necessarily central to these activities.

"But yes you know who who was in charge if the case. Me or who? Who was actually the person who should have been monitoring the sugars and checking up. Should have been me but they were doing the day to day stuff weren't they." (General practitioner, Case 398, 831, *verbatim*)

Finally relationships with specialists were perceived to be changing, with some, but not all general practitioners responding to expectations that general practitioners would adopt a much bigger role in looking after patients with long term conditions.

"All right, if they had asked us to act then we would have taken the action or something like that" (General practitioner, Case 392, 634, *verbatim*)

6.5.1.2 Inadequate systems Although new systems were being put in place to help manage new demands and expectations, the performance of these systems was not assured and there were many examples of failings that might have been addressed through improvements in systems or their maintenance:

All practices in the study were using computers. No practice was completely paperless at the time of the study and many were running parallel systems of written and electronic notes. This led to particular difficulties in tracking clinical data and particularly in linking information from general practice consultations, medication records and hospital correspondence.

"So there is lack of correspondence between the paper notes and the computer, and you might go on the computer notes and not see that there is disparity between the two." (General practitioner, Case 394, 138, *verbatim*).

Computers were consistently used for prescribing and some systems included hazard warning systems, though guidelines were generally paper-based and inaccessible during consultations and hazard warnings could be ignored.

"It would have happened probably the first time the aspirin was prescribed, you know that's back in 2001 after seeing the first cardiologist. The first time that aspirin was prescribed it would have said um "hazard" and likewise, the first time clopidogrel was prescribed, it would have said "hazard". Not sure if it says that on every occasion, I would need to check that. But yes, the system would give hazard warnings." (General practitioner, Case 355, 281, *verbatim*)

Systems for anticipatory care and chronic disease monitoring were generally in place, but again, there were clear opportunities for them to be further developed so that their performance was improved. Reminders for medication review drove much of the chronic illness monitoring, registers were not effectively integrated into systems and were often incomplete.

"Alright, because its heart failure we count as CHD register. Er sadly she has not been put on. I don't know why. OK." (General practitioner, Case 393, 452, *verbatim*)

6.5.1.3 Policy implementation Adoption of evidence based medicine and access initiatives emerged as areas where new policy directions had been adopted by general practitioners, but with mixed effects on patient care. In the first example, principles were understood, but application was inadequate and in the second application was adequate, but principles were not understood:

The evidence based medicine paradigm was identifiable in discourse from general practitioners. In both case studies where patients had suffered gastrointestinal bleeding as a result of non-steroidal anti-inflammatory drugs, doctors had considered risks and benefits and alluded to acknowledged national guidelines.

"... did consider the partial gastrectomy the patient had but this was done in 1953 and the patient had been asymptomatic. Although in 1995 he had a period of acid regurgitation on lying down for which he was prescribed Losec. ... this was a common

problem for patients, but he only had one episode." (General practitioner, Case 139, 102, *interviewer's notes*)

"Well, she hadn't had any symptoms, so there's not really any reason to think about giving her a PPI inhibitor, which I suppose is what you are thinking about, you know omeprazole or lansoprazole or anything like that. So she never complained of belly ache or anything like that." (General practitioner, Case 355, 194, *verbatim*).

Yet, in both cases clinical judgement had overridden the evidence and post hoc justification for decisions centred on notions that evidence from guidelines did not necessarily apply to individual patients.

Effects of interruptions on concentration and the course of the consultation emerged across case studies and one general practitioner argued that the implementation of changes to address access issues had brought untoward consequences by adversely affecting the work environment. One particular example related to telephone interruptions, but other schemes for improving access could also result in a more stressful working environment and longer hours for providers, which could then impact on healthcare outcomes.

"... this was a practice that encouraged patient contact via multiple access methods. That is patients could consult over the telephone too, usually indicated by a T in the notes. Usually the GP would record the consultation immediately after it had taken place but sometimes this would not occur because the doctor would be required to do something else. The GP commented that the wider access policy was not always necessarily a good thing." (General Practitioner, Case 139, 65, *interviewer's notes*).

6.5.2 Providing care in the community

Of the seven case studies, four featured patients who considered themselves housebound. There were important insights into GP home visits as a vehicle for delivery of care, into nursing contributions and modes of working, and into the way that medical and nursing staff worked together to manage this group of patients.

Community pharmacists provided additional inputs to care in the community but made a limited contribution to the care of housebound patients.

6.5.2.1 Home visits as a vehicle for delivery of care General practitioners identified practical difficulties around extending systematic care from the surgery into patients' homes. Care delivery was constrained by issues around time pressures and the extent to which practice based systems and examinations could be extended to the home visit situation:

Practices often shared responsibility for home visits by allocating particular doctors on particular days. This was a way on managing workload across the medical staff, but with associated consequences for continuity of care.

"It was very important for morale because if you have home visits coming in and there are arguments over which doctor is responsible for that patient. Is it the person who last saw them or is it the person who knows them best. Or is it the person who has been in the practice the longest then morale starts to drop really quickly because you are arguing over responsibility. If you are just responsible for the patients that present as home visits on one day there is no arguments over responsibility and it helps, there is no question. And that helps enormously. It is a relatively small sacrifice of lack of continuity for one person at home is hugely outweighed by the benefits to the practice. I would not go back for love nor money." (General practitioner, Case 394, 102, *verbatim*)

There was a sense that a consultation carried out in the home visit situation was subject to constraints imposed by practice information systems, which could exacerbate continuity of care issues. Sometimes practitioners visited without the patient's notes, and increasingly, written notes were inadequate as practices transferred from paper based to electronic recording.

"Exactly, the problem is coming up more frequently now. Because that used to happen quite a lot that there was a little bit written on computer a lot written in the notes so that when on a home visit you used to have quite a lot of confidence that you had all the information in front of you. Now it has turned completely opposite. Everything is on

computer. We take the written records to the patients' house but they have none of the updates consultations from the GPs surgery and they have none of the current medication so it is harder to see what is happening to the patient over the last few consultations when you are now seeing them in their house." (General practitioner, Case 394, 140, *verbatim*)

The general ethos seemed to be towards dealing with presenting complaints underpinning requests for home visits, rather than attempting to replicate a more holistic approach to care that might be an aspiration in the surgery situation.

"That was done by another person. Um and I am just thinking in terms of detecting a potential um problem is the fact that this was a home visit and she did not present to clinic." (General practitioner, Case 392, 837, *verbatim*)

For simple, intercurrent problems, telephone consultations might be adopted.

"12th November telephone with sticky eye and she was given some eye drops. 26th November telephoned low sugar today. District nurse has been today and BM was 4." (General practitioner, Case 389, 420, *verbatim*).

Occasionally an ambulance might be called to attend to a patient without actually visiting.

"Erm on the 26th November she had a hypoglycaemic attack. And that was rung through to us by the district nurse. And that's when they called an ambulance... and it looks like..." (General practitioner, Case 389, 48, *verbatim*).

Where care needs were likely to be complex and ongoing, then the response might involve attempting to renegotiate the possibility of the patient visiting the surgery and/or soliciting the assistance of carers. Only when these options were exhausted, would the general practitioner make contact with district nursing colleagues to assist in tasks related to chronic disease management.

6.5.2.2 ***Nursing roles and boundaries*** The provision of continuing health care to patients in their own homes was fundamentally dependent on the contributions of the district nursing workforce. In this study, district nurses made an important contribution to medication management amongst patients. They participated in a more limited way in other aspects of chronic disease management and were often seen reasserting boundaries in relation to this:

A crucial role for district nurses in one case study was the administration of insulin to a patient who was unable to administer her own.

"And erm er but she also had very failing eyesight and er we erm we started by visiting her... we were visiting her I think once a day for administration of insulin" (District nurse. Case 389, 29, *verbatim*)

This they accomplished with support from a diabetic specialist nurse and with rather less input from the general practitioner, except where that support broke down, or in emergencies.

"And they would liase with the with the district erm, with the diabetes nurse as to how to change the dose and if they couldn't get hold of them I suppose they would call us and if she was having a hypo. I mean I think I came in a couple of times and changed the dose if she was having hypos and I juggled the morning dose." (General practitioner, Case 389, 127, *verbatim*).

In addition, district nurses were receiving referrals from general practitioners to assess patients who might have medication administration problems.

"Otherwise at times if we have (problems) like that I just ask district nurses to do blisters for them" (General practitioner, Case 392, 1027, *verbatim*)

Any further remit in chronic disease management appeared more restricted. District nurses might respond to requests from doctors to take blood or make routine observations including blood pressure, weight and pulse in housebound patients, but the

latter was "by negotiation" and usually on the assumption that the input was over a limited time frame- as part of their "caseload".

"There is one um episode documented here on 16th August. Taken by ..... my colleague over there. She was on methotrexate and this is why..... She also had blood taken on the 9th. Sorry, the 9th and the 16th August. She was being seen by the rheumatologist..... " (District nurse, Case 133, 171,*verbatim*)

Personal relationships and the normative behaviour of teams could also make a difference, but generally it would have been unusual for a general practitioner to be able to persuade a district nurse to assist in a diabetic annual review for example.

"I tell you what... I would if... I would like it if the district nurses, for the housebound patients, could come and do regular reviews because at the moment we haven't got a practice nurse (who might do that)." (General practitioner, Case 295, 751, *verbatim*)

6.5.2.3 Working together Where medical and nursing staff were both involved in addressing continuing care needs of a patient, working arrangements appeared more consistent with a pragmatic alliance than true team based care:

General practitioners might acknowledge responsibility for the clinical care of patients, but were unlikely to a identify themselves in a leadership role in relation to teams.

"But most I mean thinking back I would see her occasionally but most of the time it was the liaison between the diabetic specialist nurse with the insulin and the district nurses who would give it. That was where most of the care for her occurred. I mean looking back I don't know I can go through some of the consultations erm but yes you get urinary tract infections, which is quite common. Chest infections for which I would treat her. So in November 2002 a couple of months before she died she, she had er a chest infection and than a urine infection couple of weeks later." (General practitioner, Case 389, 46, *verbatim*).

One of the general practitioners in the case series described team meetings, but there were clear indications that such meetings were always at risk from the pressures of daily work, or the relocation of professional groups.

"No I would not say that because we do have meetings with the district nurse. In theory they use to run very efficiently because the district nurses used to come and do clinics here so we would bump into them always every day they would be picking up scripts at reception and we would see them all the time. We could keep up with the kind of the immense amount of information that there needs to be between the two. (General practitioner, Case 394, 182, *verbatim*)

Instead, a range of modes of communication would be employed in the hope of keeping relevant parties informed within a less than perfect framework, and with some predictable consequences. For nursing staff, nursing notes kept at a patient's home were a primary document, to which general practitioners might also on occasion add.

"And you know yes we encourages everyone to write in the (nursing) notes really you know that's what you know erm if erm it is just great that ... actually wrote in the notes here. You know." (District nurse, Case 389, 963, *verbatim*).

Facsimile was also commonly used. This was particularly useful for districted nurses working at health centres distant from a patient's general practitioner and was also used by the specialist diabetic nurse in keeping everyone informed of medication changes that she proposed.

"And er (specialist diabetic nurse), if (specialist diabetic nurse) is visiting people at er she is very particular if she is visiting people you know in their own homes or if she if she's er she writes in the notes and she will fax us and she would fax the GP. So everybody would be you know. (District nurse, Case 389, 983, *verbatim*).

In one case study, a pharmacist had attended meetings at the patient's practice. However, for most pharmacists the links back to the patient's practice were by telephone, typically to raise questions about specific prescriptions they had been asked to dispense.

"But this one doctor.. So I rang the doctor and said no, this is OK, please make it... change it to half a dose or whatever. Yes we have to interfere at times." (Pharmacist, Case139, 567, *verbatim*)

6.5.2.4 Pharmacy care The possibilities of pharmacy care have been expounded and celebrated over recent years. The experience of this research was that pharmacy care was focused mainly on checking prescriptions as issued, counselling on new drugs and informal advice, with less attention paid to compliance and monitoring. One pharmacist was offering a range of additional services, but this appeared to be an exception rather than the norm:

The typical contribution of community pharmacists was to provide informal advice to patients at the time prescriptions were issued.

"Oh yeah, most of the time. Because we tell them that look ok, I know you are taking it for this thing but you can't take it with an anti-inflammatory. You must be careful if you are allergic to ... Sometimes people don't even know they are allergic to aspirin. And if they take that you know that also could affect it. So we tell them that and if you are taking and it is affecting you because sometimes they say –oh the doctor told me to take it. Sometimes" (Pharmacist, Case 139, 175, *verbatim*)

One pharmacist said that his better known patients called him for advice.

"Sometimes if I know them really well. If they have problems.. if they got problems... if we have to talk to them a lot we have the telephone number on there" (Pharmacist, Case 295, 430, *verbatim*).

The same pharmacist also provided some extended services, including smoking cessation and was involved in a pilot project for pharmacy based anticoagulation monitoring. He went on to describe how he often became engaged in an educational role with patients with diabetes for example.

"They often disclose erm, you know, if they are putting on weight and are they on the right tablet and all that sort of stuff you know and or if they have had a change. It is usually a change that will trigger me into a conversation" (Pharmacist, Case 295, 430, *verbatim*).

Other pharmacists indicated that the pharmacy itself could be a poor environment for medication counselling, let alone providing extended services:

"I would say that generally I, one of the problems... problems for me is that I always seem to be fairly chaotic and I, it's busy and erm I find it difficult just to get through the day really. And that's not an excuse... but well it is an excuse, but it's a good excuse really. Er and think erm giving them a lot of time at the counter is really difficult" (Pharmacist, Case 295, 599, *verbatim*).

Pharmacists generally had a register of patients whom they provided prescriptions for, but these did not seem to be used for monitoring and were subject to various constraints. They were often incomplete and in one pharmacy all records were archived every three months. Sadly, patients who were housebound missed out on all opportunities for medication counselling and advice:

"Before yeah we had her but way back ...last time was February in er this year so she's had a big long gap" (Pharmacist, Case 295, 192, *verbatim*).

"But you know you just can't tell what's gone... If you don't see any one you don't know. The background to why you are missing them... " (Pharmacist, Case 394, 307, *verbatim*)

6.5.3 Working with hospitals

Interactions between primary care staff and hospital teams featured in all case studies. Issues around sharing care and the impact of specialisation on patient care frequently emerged as themes that related to the quality and safety of care. While the concepts of sharing responsibility and specialisation were not usually overtly problematic,

communication issues consistently impacted on the way that the concepts were translated and enacted.

6.5.3.1 Sharing care Five of the case studies involved patients in which specialists were providing ongoing care to patients through the hospital outpatient system. A range of shared care patterns was identified, each involving different relationships and responsibilities between general practitioners and hospital teams.

In one case study, the general practitioner acknowledged no transfer of responsibility to the hospital team that interacted with his patient in the outpatient department. This general practitioner identified the specialist's role as providing advice and assumed that the responsibility to act on that still lay ultimately with the general practitioner.

" (The cardiology registrar) was not prescribing them, he was recommending them. And she wasn't under the care of the cardiologists. The cardiologists had seen her in association with a pacemaker problem, noticed the atrial flutter, said this woman ought to be on aspirin, then suggested you add in clopidogrel.." (General practitioner, Case 355, 214, *verbatim*)

In a second case study, the responsibility for the patient was shared, with the general practitioner acknowledging responsibility for the day to day care of the patient and periodic review at the hospital clinic.

"Well I suppose that was me. Erm I suppose that was me but I think she was under the diabetic clinic as well. Look, I suppose that was me so I was doing the average HbA1 but she was um she was last seen, she was under ... er and the last time she was seen ... for her diabetes was 4th September 2001. So she was under ... was swa... swapping her...was that a year... that was a year before." (General practitioner, Case 389, 484, *verbatim*).

In a third case study, relationships and assumptions were different again. The general practitioner assumed that a hospital department took complete responsibility for initiating and monitoring a patient's treatment until a decision was taken to discharge

them from hospital care. In this particular case, the general practitioner issued prescriptions, but assumed no responsibility for reviewing the patient.

"So there was no need for me to follow it up, because it was not left...over a long term. (Thinking aloud) "We have discharged her and that is the end of you...the doctor will take care... ". Because she was followed up regularly at the cardio... ". (General practitioner, Case 392, 439, *verbatim*).

Evidence from the case studies suggested that that the process for establishing the boundaries of responsibility in cases receiving care through hospital outpatient departments was transactional. Assumptions were made on the part of the hospital team and on the part of the general practitioner as to how they would work together, but these assumptions could be challenged. In one case study a mismatch between the expectation of the hospital and that of the general practitioner led to some distress and confusion.

"But at times they see them early or anything like that. If there was an abnormal thing or we have noted this abnormal thing and we are not clear now what is going to happen to this patient. Is she going to be followed up, to be...Plus seeing her age and her heart, well this...I am now thinking, right, of this thyroid. Do we start her thyroxine in the community? Or do we ask a specialist to look at (her) because of her heart condition. Which can precipitate her angina or anything like that. How much dose to start at the age of ninety two?" (General practitioner, Case 393, 701, *verbatim*)

In another case a mismatch of expectations led to problems initiating monitoring in a patient taking methotrexate.

"... not sure how monitoring would occur if done by district nursing. Does not have any patients like this. Blood test results would be fed back to the GP who would then inform the hospital of problems so introducing another layer of problems because the GP is not empowered to.... Not aware of any protocol currently in place for district nurse-GP liaison in this area." (General practitioner, Case 133, 110, *interview notes*)

6.5.3.2 Specialisation Although access to specialists might be initiated by general practitioner referrals, there were other points of entry. These include referrals from A&E, referrals from teams that had admitted patients and consultant to consultant referrals through the outpatient department.

Some general practitioners appeared not to understand the process, or the extent to which medical teams took opinions from specialist colleagues.

"And that is what happens. And er I don't know why one time we have a letter from Care of the Elderly. Then we have the cardiac clinic. I don't know." (Case 392, General practitioner, 513, *verbatim*)

Others were surprised that hospital admissions teams felt it necessary to bring in specialists to review patients with conditions that general practitioners themselves were quite familiar with:

"She was admitted in November under another team with presumed UTI; "thankfully she was also reviewed by our diabetic registrar who picked up maculopathy."" (General practitioner, Case 389, 288, *verbatim*)

General practitioners could see specialisation as a double-edged sword, bringing risks as well as benefits to patients receiving hospital care:

"The real worry is that specialists sometimes have blind spots. They think about cardiology and they think about heart conditions, and um, they don't necessarily think about the other problems a patient has, and you know it could be that whoever saw the patient hadn't thought it all through. It was actually a fairly junior doctor who saw the patient and made the recommendation, though it does say in the letter that it was discussed with the consultant." (General practitioner, Case 355, 316, *verbatim*)

As clinicians responsible for the "whole" patient they could express surprise when problems were "missed" by hospital colleagues and could feel that they could have a difficult task assuring that aspects of the patient's care did not get neglected:

"Normally cardiologists should check the whole of the vascular system. Erm, so you would have thought they would also have checked her feet." (General practitioner, Case 295, 341, *verbatim*).

"She was seen by the opthalmologist the week before she was admitted to hospital. Which is all a bit sad if they picked up maculopathy a week later but nobody was responsible for... She was being seen by the eye clinic at the hospital." (General practitioner, Case 295, 290, *verbatim*)

When referrals were made between specialists, then general practitioners could feel even more disenfranchised as co-ordinators of care:

" So (the patient) was referred to (name), a consultant urologist. He also orchestrated the cancer care and referred (the patient) to a consultant general surgeon (name) for treatment of the gallstones. So that practice was not really involved in that aspect of care."(General practitioner, Case 139, 77, *interviewer's notes*)

"And she had an angioplasty although we have no letter from them saying that she has had an angioplasty. And this, this just makes me...." (General practitioner, Case 389, 477)

6.5.3.3 Communication and the interface Amongst patients receiving hospital care, the greater volume of communication was from the hospital team to the general practitioner, and principally through the medium of letters. Timeliness and content were themes arising frequently in relation to letters as a communication medium. Telephone was sometimes used for communication, but this approach could also have its pitfalls.

Historically, discharge letters were hand written. Patients were asked to deliver a copy to the general practitioner, while another followed in the post. A policy of faxing discharge letters (that included discharge medications) was introduced during the study period, which addressed the issue of timeliness, but discharge letters remained brief and without detailed management plans.

"And the other thing was the the hospital. I mean er the discharge letters from the hospital weren't very good. Er you know erm again that is something probably that we should have been a little bit more proactive and and set up a better dialogue with the hospital you know. When she was admitted. Maybe we should have followed it up by phoning them." (District nurse, Case 389, 1179, *verbatim*)

Management plans would come later, for patients who were followed up in the outpatient department. The outpatient letters were more detailed, but might be slower to arrive. Thus, one general practitioner described how a patient's son would be the principal medium of communication between the outpatient department and general practitioner, relaying medication changes in advance of correspondence arriving.

"And when any changes were made by the cardiac team the son would let us know." (General practitioner, Case 392, 144, *verbatim*)

It is possible that telephone communications may serve as a more reliable communication medium than letter for some shared care interactions and certainly this appears to have been the medium used for the most immediate and important communications:

"Yes, cardiac clinic. Her renal function had markedly deteriorated. So we admitted to stabilise her the following day. On the 27th. On the 27th I had a phone call... because the blood test was done on the 26th in the clinic. Which showed a potassium of 7.1" (General practitioner, Case 392, 48, *verbatim*).

Access issues for telephone interactions need to be resolved however. Two areas of concern were raised by general practitioners. Firstly, access to consultants was usually via their secretaries, who themselves might be temporary staff who general practitioners did not necessarily feel they could rely on:

"A pretty desperate situation. The consultant is not there. The secretary is a temp secretary.." (General practitioner, Case 392, 987, *verbatim*)

Secondly, junior staff, who were accessible by pager, were often on short contracts or rotations and would be unfamiliar with specific patients. Time spent trying to identify an individual who would respond to a query could be a considerable source of frustration.

"Well the sad thing in ... this scenario is that the registrars or SpRs of SHOs they are not the right one they have left the job and you are just going round in a circle."
(General practitioner, Case 392, 975, *verbatim*)

6.6 DISCUSSION

6.6.1 Summary of main findings

Sixteen interviews relating to seven case studies were analysed. Each case study investigated circumstances surrounding a medication related admission in an older patient that was judged preventable by a multidisciplinary panel. Seven types of active failures emerge as relevant to the genesis of medication related problems. Typically three or four care management problems contributed towards each adverse outcome. Care management problems were mostly explained by higher level factors operating at the levels of systems, the work environment and the effect of policies and organisational management. A grounded analysis of the interviews generated a series of themes, which broadly related to general practice in a state of transition, providing care in the community and working with hospitals. Domains of general practice culture and organisational systems, interprofessional working, communication, responsibility and specialisation emerged as areas where clarification, development and implementation could lead to improvements in the quality of care.

6.6.2 Strengths and weaknesses of the study

The critical incident approach is a useful framework for assuring the collection of key information relating to particular outcomes. As it focuses on the retrospective

investigation of incidents it cannot establish cause and the method cannot determine how common a particular circumstance is. The research is based on a small number of case studies that may not be representative of preventable medication related admissions. By using multiple informants involved with incidents it was possible to assure a level of internal validity and the experience of the informants and the principal investigator in healthcare environments brings some external validity to findings and interpretations.

The scope of the human factors approach is broad and the framework has great explanatory power, but the structure itself can place constraints on the generation of new ideas. In contrast the grounded approach is atheoretical, assumes nothing about the structure of the data, and seeks to interpret, link and challenge the narrative of informants and to create new theory. The validity of the approach is dependent on the ability of the investigator to step back and ask critical questions, to be sensitive to the words and actions of the informants, and to challenge and test assumptions by returning iteratively to the data (Strauss and Corbin, 1998).

In this study informants made valuable direct observations on interactions with people, systems and work environments that had implications for patient safety, but they did not often spontaneously attribute effects at this level to the broader contexts in which they worked. The importance of key organisational constructs did emerge particularly in the grounded analysis with consistent topics and themes identifiable across informants and across case studies. Applying the human factors approach and then reanalysing the data using constant comparison generated complementary findings and strengthened the study overall.

Some health care staff expressed concerns about the potentially sensitive nature of the material discussed, and this was particularly true of informants in secondary care settings. Most informants however, were open to admitting that there might have been problems in care delivery, and willing to reflect on the reasons why this might have been so. Safeguards were included in the research design to build internal and to assure external validity in the analysis and interpretation of the data and these bring confidence to the findings of the study as a piece of qualitative research.

6.6.3 Implications of the research

The human factors framework has previously been applied to the investigation of incidents in healthcare settings. Studies have been done in obstetrics (Taylor Adams *et al.*, 1999; Stanhope *et al.*, 1997), psychiatry (Vincent *et al.*, 2000) and nursing (Meurier, 2000). Typically papers have described single cases, investigated using the human factors framework developed by Vincent and colleagues (Vincent *et al.*, 1997) and no previous work has been done in primary care.

In this study, the human factors approach was applied to a series of cases in primary care settings and provided a useful framework for the analysis of problems in medication management and the causal factors that contribute to them. As in earlier work, detail emerged that showed how acts and omissions are themselves likely to be the product of constraints operating at the level of systems or organisations. (Vincent *et al*, 2000; Stanhope *et al*, 1997). The case studies showed how contributory factors are interrelated and how between them they more or less inevitably lead to suboptimal care. Our findings are consistent with "normal accident theory" (Perrow, 1984) which argues that complex systems inevitably generate situations that can lead to adverse outcomes. The health system at the time of the study would be considered a loosely coupled system, that is one where frequent breakdowns in flows of information, tasks or processes are dependent on human players to recover the adverse consequences of system problems (Perrow, 1984). This research points to issues around clinical judgement, tensions between professionalism and the impact and development of managed systems, joint working of general practice and the extended primary care team and with specialists as areas that harbour problematic and sometimes hazardous situations for patients.

To understand how or why these areas of activity translate into problems it is may now be appropriate to move beyond the medical quality knowledge base and to draw on social science literature outside healthcare, including sociological and human factors research. The complexity and connected nature of the organisation of healthcare means that human performance themes will be found wherever a problem occurs. Errors or adverse events that appear similar may be underpinned by very different sets of

circumstances. Similarly the same human performance issues might play out and result in a range of rather different outcomes for patients. This implies that further research studying specific human performance issues could lead to important insights and improvements in healthcare quality that to date studies of patient safety in primary care will have missed.

7. DISCUSSION AND CONCLUSIONS

This thesis comprises a series of linked research studies directed towards the cause of improving patient safety in primary care. The research objectives were to understand the methods available for the investigation and analysis of clinical incidents in healthcare and then to draw on understanding of method to investigate the scope and causes of medication related admissions in older people. These adverse events supported a focus of investigation that could enable specific learning on medication management issues and generic learning on quality and safety issues in primary care settings. This chapter draws together the findings of the research presented in preceding chapters. The findings are summarised in the context of the specific objectives of the thesis. The methodological issues arising in the thesis and then the implications of the findings of this work for service delivery and research are discussed, leading on to a series of conclusions.

7.1 SUMMARY OF PRECEDING CHAPTERS

7.1.1 Chapter 1

This chapter introduced the aim of the thesis, which is directed towards exploring in a systematic way, the fundamental structural characteristics of general practice that can have a bearing on patient safety. The specific objectives reflect the need to evaluate methods used for investigating incidents in health care and to test a method for use in primary care, and to initiate an occurrence screening study that would provide context and sampling frame for subsequent case study work. The policy context of the proposed research is included through reference to a series of documents that emphasise the importance of investigating incidents and of improving the safety and effectiveness of medications management in primary care.

7.1.2 Chapter 2

Chapter 2 provides historical background to the development of clinical governance and the emergence of risk management in the National Health Service. The importance of medication safety and the scale of the problem of medication related admissions is introduced. Information is presented on adverse events associated with medical management in the general practice setting. Then factors that might explain the occurrence of such events are explored, before moving on to a discussion of approaches which might be adopted by individuals, or by organisations to help avert their occurrence. These include the use of clinical guidelines, early work with decision support and shared decision making; analysis of complaints, case based and topic based audit, quality assurance through pharmacist support and some examples of continuous quality improvement; and the contribution of undergraduate and postgraduate education. At the time of writing there was little evidence for the implementation of proactive risk management approaches in general practice.

7.1.3 Chapter 3

Analyses of accidents in high-risk industries have led to a much broader understanding of accident causation than can emerge from identifying individuals at fault. This chapter describes a systematic review of methods for the investigation and analysis of critical incidents in healthcare. Well established methods have been developed for application in major studies and in some health systems, to identify patterns of occurrence or recurrence of events, through reporting, synthesis and analysis. Other approaches have been applied primarily in the investigation of a single or small series of events and are likely to be most useful for local investigations with a view to understanding events and securing improvements. In an evaluation of methods against specified criteria, root cause analysis and organisational accident causation methods were judged to have good levels of consistency and scope. The latter, grounded in the human factors approach also had the benefit of theoretical adequacy against accident theory and in the complexity with which the outcomes are formulated.

7.1.4 Chapter 4

The human factor approach as conceptualised by Vincent (1998) was developed and applied in the investigation of a series of clinical incidents in primary care settings. Primary care stakeholders identified with the approach and found the human factors framework helpful and easy to apply. The analytic framework could be applied effectively to adverse events occurring in primary care settings and generated a range of insights into factors that contributed to incidents. Particular issues emerged around data collection in the primary care setting. General practitioner informants were key to assembling chronologies, with written and electronic records thin in detail. Other community staff may be geographically and managerially separated from general practitioners necessitating additional effort to assure access. Identifying a series of incidents for investigation was not straightforward and in part informed the nested design for the study described below. A published protocol was adapted and simplified for primary care use, and comprised the guidance for subsequent in depth case studies

7.1.5 Chapter 5

Medication related admissions in older people comprise a significant public health problem. This adverse outcome can usually be attributed to medication related problems emerging in the primary care setting. In a study using an occurrence screening design, 14% of older people admitted to the medical admissions unit of an acute hospital had medication related problems. In 6% of patients these problems contributed to the admission and about 4% of admissions were judged preventable. Cardiovascular system drugs were most often involved and the commonest outcomes associated with admissions were cardiac failure and gastrointestinal bleeding. The complexity of the case as assessed by the number of past medical history diagnoses and the number of drugs on admission predicted the medication related admissions associated with under treatment and adverse reactions respectively. This research provided the context and the sampling frame for the case series focussing on causes of preventable medication related admissions described in the next chapter.

7.1.6 Chapter 6

A critical incident approach was adopted to bring focus to a series of cases where things had gone wrong. Case studies were assembled and analysed. A structured analysis derived from accident theory was applied then an open coding approach with constant comparison to identify and illustrate contextual themes. Typically three or four "active failures", or care management problems were identified as contributing towards adverse outcomes. These were mostly explained by higher level factors operating at the levels of systems, the work environment and the effect of policies and organisational management. A grounded analysis of the interviews generated a series of themes, which broadly related to general practice in a state of transition, providing care in the community and working with hospitals. In particular, organisational systems in general practice, inter-professional working, communication, responsibility and specialisation emerged as areas where clarification, development and implementation could lead to improvements in the quality of care. The chapter concludes with the message that research studying specific human performance issues could now lead to important insights and improvements in healthcare quality.

7.2 METHODOLOGICAL ISSUES ARISING IN THE THESIS

7.2.1 Systematic review

The importance of reviews as a guide to researchers, practitioners and policy makers is widely recognised (Mulrow, 1987; NHS CRD, 1996). Systematic reviews were originally applied almost exclusively to questions of effectiveness of healthcare interventions, and so to randomised trials. Increasingly the approach has been adapted to the appraisal and synthesis of results of non-experimental designs and increasingly to qualitative research (Fleiss and Gross, 1991, Lemmer *et al.*, 1999). The review featured in this thesis is characterised by a focus on investigative methods, rather than outcomes of interventions, and draws on materials from different published media and across a range of study designs.

There were a larger number of potentially relevant studies for review than originally expected. As the objective of the review was to map and describe methods, no attempt was made to appraise and present every paper. Rather, an iterative approach was taken to creating a classification of methods, with purposive sampling of publications for appraisal and synthesis. The study design served the objectives of the review within an acceptable time frame, but does not support statistical comparison of the detail of methods or analysis of trends.

It should also be noted that the final classification of techniques is not exhaustive. This analysis effectively excludes a large body of literature comprising complaints, case reports and regulatory reports that provide narratives on incidents, but without reference to any particular investigative technique or approach. Techniques with smaller numbers of publications were also excluded, though this does not imply that these are not of value. Also, there were studies that adopted hybrid designs, such as root cause analysis nested within a confidential inquiry. This is somewhat lost in the classification of which assumes that particular techniques are rather more distinct than may be the case in practice.

Finally, the approach used to assess the adequacy of the techniques still requires independent validation. Fahlbruch and Wilpert (1997) have provided guidance on assessing theoretical adequacy of accident investigations and Benner (1985) and Kirwan (1992) have evaluated models and techniques for investigating accidents in various settings. This work informed the development of the instrument described. Under the conditions of use imposed by the review, the approach appeared to have face validity and there was good consistency between individuals involved in assessments, but more formal validation of the approach, as an assessment tool would be useful and appropriate.

7.2.2 Occurrence screening study

Some of the most important studies in the patient safety field have used an occurrence screening design. These have included the Harvard Medical Practice Study (Leape *et*

al., 1991) that involved a review of over 30,000 cases admitted to hospital in New York State in 1984. In 1992 a similar study was conducted in a sample of hospitals in Utah and Colorado (Thomas *et al.*, 1999) and in Australian hospitals (Wilson *et al.*, 1995). These broad studies that have provided estimates of the scale of unintended injury to patients have been powerful drivers for change. The approach taken is epidemiological and the objectives of such studies have been to measure the scale, subgroups, severity and avoidability of adverse events.

In this thesis an occurrence screening study was used to establish the size and nature of the problem of medication related admissions in older people. The design would provide contextual information and a sampling frame for case studies of preventable medication related admissions in older people. This was a small scale study compared with the studies cited above, but of adequate power to support estimates and exploratory logistic regression. The occurrence screening study was conducted over a three month period, and the sample was broadly similar to the population from which it was drawn.

The pharmacist used an established instrument to identify medication related problems, and pharmacist performance was assessed during and after training to assure accuracy and consistency. A multidisciplinary panel took final decisions on attribution and preventability. However, the specialist registrar presented only cases where the medication related problem was judged contributory to the admission to the panel, which implies that the final estimates might be conservative. Panel discussions were sometimes lengthy on issues of preventablity, especially when considering expectations on health systems and estimates of preventable medication related admissions might also be conservative.

The scope of medication related problems was wider in this study than in some others with a similar purpose and design (Malhotra *et al.*, 2001; Cunningham *et al.*, 1997; Hallas *et al.*, 1991; Chan *et al.*, 2001). Failure to prescribe indicated medicines was included in the definition of medication related problems. This operational difference as well as the threshold effects described needs to be taken into consideration when comparing the findings of studies.

7.2.3 Investigations in primary care

The thesis describes the development and application of one particular technique for the investigation and analysis of incidents in a primary care setting (Vincent *et al.*, 1998; Vincent *et al.*, 1999). The choice of technique was informed by the systematic review and was piloted in primary care settings before its use in a definitive research study. The acceptability and appropriateness of the technique amongst primary care stakeholders was assessed through presentations and interactive workshops. These activities were necessarily exploratory and evolutionary. Evaluation was reflexive and based on participant observation, written notes and evaluation materials. Subsequently a series of incidents were investigated in primary care settings. Experiential learning from the process of conducting inquiries in primary care informed the design and implementation of the subsequent research.

It was clear that general practitioners would be crucial to the process of assembling case histories using the approach, not least because case records in primary care were often inadequate to the task, and at the time of the study, partly in written and partly in electronic media. Extending the inquiry to other informants could expand, consolidate and validate the case history, the interpretation of what might have gone wrong and what the contributing causes might be. The interviewer was trained for the task, but even with prior experience there was evidence that competency continued to improve. In particular the interviewer became more efficient at eliciting relevant information as she learned to work more flexibly around the guidance and began to explore cognitive interviewing techniques.

Guidance was drawn up for the investigation on clinical incidents in primary care settings. A consultation panel emphasised the importance of assuring that the guidance contained practical detail on conducting investigations and was presented in simple language with a one page "how to do it" card. Worked examples were to be included and a section linking the findings of investigations to action points for people and organisations involved was to be developed.

7.2.4 Analysis of investigations

In the earliest case studies, case histories, interpretations of problems and contributing factors were based on the investigators findings supported by contemporaneous notes, an approach that was true to the method described by Vincent *et al.* (1999). Initially as a means of communicating the nature of the investigations but also as an opportunity to check detail, case reports drawn up by the principal investigator were shared with informants and comments were sought.

In the research study described in Chapter 6, interviews were audio taped whenever permitted and text that informed the analytic interpretation was tagged as supporting evidence. Case histories represented a synthesis of the accounts of all informants and the interviewer and the principal investigator performed analyses independently before agreeing a final version. Lastly, all informants were asked to verify the accuracy of the reports.

While there was considerable evidence of informants directly identifying lower level contributing factors as relevant to incidents, they were less likely to specifically identify contributions of higher level factors, in the domains of organisational management and policy. They did nevertheless commonly describe situations where higher level factors contributed to the adverse outcomes. When the text was analysed using formal qualitative methods it became clear than this incorporated additional rich descriptive material of considerable relevance to the objectives of the thesis.

The classification and relations of the broad domains and themes described in this research was emergent, albeit with measures in place to assure consistency through independent coding of a selection of interviews. The study design did not support sampling to extinction as in classic grounded theory and the results of this analysis have not been validated by subsequent interaction with informants. As such the findings of the research are provisional and mainly descriptive. The key findings will require external validation against existing literature and new research.

7.3 IMPLICATIONS FOR RESEARCH AND PRACTICE

7.3.1 Developing techniques for the investigation of incidents

While all the healthcare techniques for the investigation and analysis of incidents are of value and have much to contribute, it is important to recognise that they will be applicable in certain contexts. An important point that emerged from this research is that authors of both individual studies and developers of techniques and methods need to specify the purpose of their approach much more clearly. Equally important, the context of use should also be specified. Some indication should be given as to whether an approach might potentially transfer as a technique and how adaptable or transferable it might be to other settings.

Researchers need to provide much more detail on the process of investigation, either by developing separate documents, or by providing more detail of the study methods. Some methods, such as the protocol of Vincent *et al.* (1999), were originally designed with an individual investigator, usually a risk manager, at the heart of the process. However this is only one way of approaching an investigation, and the technique has also been used in other formats, such as structured team discussion and in training and education. Those developing or using techniques should specify the way in which it is to be used, or give guidance on any changes in approach which might be necessary according to whether the process is researcher or investigator led or whether it is a team based group discussion.

In general, the level of resource to support investigations in healthcare is far outstripped by the situation in industries outside healthcare. Developers of healthcare techniques need to provide manuals and protocols. These are available for root cause analysis and organisational accident causation models, but not widely disseminated or applied. The approaches are not easy to use without some level of training or support and organisations such as the National Patient Safety Agency in the United Kingdom will have a responsibility to assure that the resource is available. Likewise organisations providing or commissioning healthcare will need to assure that they can make the

resources available to investigate incidents when they occur.

Techniques that are sufficiently evolved would benefit from formal evaluation of their outcomes and effectiveness. While the present review has gone some way to achieving this, there is a need to mount specific studies to evaluate techniques in different contexts. Examination of context of use is vital. While it appears that all techniques are quite widely applicable, some have evolved in particular settings and need to be tested elsewhere. Exploring transferability is also important in that different techniques bring a rather different focus to understanding clinical incidents in health care. Some of the techniques reviewed provide alternative approaches to understanding problems, and hybrid designs may generate complementary findings.

7.3.2 Medication related admissions

Disease caused by therapeutic drugs has been well documented since Barr (1955) and Moser (1956) described the hazards of modern medical therapy. The importance of extending the remit of inappropriate prescribing to failure to prescribe indicated drugs has also been highlighted over recent years (Illiffe, 2000). Reviews of studies of hospitalised patients have established the rate of medication related admissions to be somewhere between 2% and 25%, with variation recognised as a consequence of methodological differences including the types of hospital wards, the definitions of medication related problems, and whether patients were interviewed (Einarson, 1999).

Seven studies have generated data on medication related admissions for patients of 65 years and older (Chan *et al.*, 2001; Malhotra *et al.*, 2001; Cunningham *et al.*, 1997; Hallas *et al.*, 1991; Pouyanne *et al.*, 2000; Raschetti *et al.*, 1999; Colt and Shapiro, 1989). All except one (Colt and Shapiro, 1989) used prospective data collection, and supplementary patient interviews were included in four (Chan *et al.*, 2001; Malhotra *et al.*, 2001; Cunningham *et al.*, 1997; Hallas *et al.*, 1991). Except for one study (Colt and Shapiro, 1989) a panel reviewed all suspected cases. Amongst the four studies methodologically closest to the one appearing in this thesis, rates of medication related admissions were between 3.4% and 7.5% (Malhotra *et al.*, 2001; Cunningham *et al.*, 1997; Hallas *et al.*, 1991; Chan *et al.*, 2001).

Not all medication related admissions are preventable and not all studies of medication related admissions assess preventability. Two reviews have been published that specifically explore preventable medication related admissions. Winterstein *et al.* (2002) identified nineteen studies featuring preventable medication related admissions and reported a median rate of 4.3% and a median preventability fraction of 0.59. Howard *et al.* (2003) using more restrictive inclusion criteria, identified thirteen studies and reported a median rate of 3.7% and a median preventability fraction of 0.56.

Howard *et al.* (2003) also summarised available information on underlying causes of preventable medication related admissions, highlighting prescribing, adherence and monitoring problems, and identifying the drugs involved. In this series four drug groups accounted for over 50% of hospital admissions. These were diuretics, antiplatelet drugs, non steroidal anti inflammatory drugs and anticoagulants and the authors argue that improvement efforts should target medication related problems attributable to these drugs. The thrust of the recommendations made is towards more rational prescribing and closer monitoring. The depth case studies featured in this thesis provide illustrations of how problems arise in medication management and both support and challenge the tenet of the recommendations that individuals need to do more to assure the safety of the patients for whom they prescribe.

7.3.3 Understanding accidents in primary care

Adverse reactions to medicines are common in older people and some medicines that could reduce illness are not always prescribed for patients who would benefit (Department of Health, 2001a; Department of Health, 2001b). Careful prescribing, monitoring and review is necessary because the potency of the drugs involved and the effects of age related changes in drug handling make older people more susceptible to drug effects. Interventions developed to improve medication safety have tended to address educational needs of clinicians and decision support, or else extended roles for pharmacists involved in dispensing drugs. Much less attention has been paid to influences operating at the level of work environment, management, organisational and

policy settings, all of which will ultimately affect interactions between clinicians and patients and between clinicians and systems in place to protect patients.

Understanding human performance in any complex setting requires a detailed understanding of the setting and of the factors that affect the way people behave. The complexity and interactive nature of healthcare means that problems in healthcare delivery can and do occur and the more complex the processes, systems and organisations to deliver care, then the greater the probability of things going wrong (Allnut, 1987). There is already a research base on human performance that has been built by understanding how human players handle challenging situations in aviation, transport, industrial and military operations. To apply the human factors knowledge base to healthcare requires a detailed understanding of how human factors issues might operate in healthcare, together with clinical knowledge of the determinants of medical success or failure (Reason, 1993).

The clinical complexity of medicine delivered in primary care is modest compared with expectations on cardio-thoracic surgeons or anaesthetists, but this observation does not apply to the organisational complexity of the environment in which general practitioners operate. To deal effectively with specific problems in healthcare requires an understanding of both human factors knowledge and medical knowledge (Reason, 1995). The studies described in this thesis comprise a first step towards that end.

7.3.4 Quality and safety in primary care

General practice provides essential functions for individuals and populations in an increasingly complex health care system. Recent years have seen an emphasis on general practice delivering public health, promoting the quality of care, managing long-term conditions and now in managing efficiency and offering choice (Anon, 1994; Pitterman and Koritsas, 2005; Ferrer *et al.*, 2005). These new policy drives are themselves superimposed on older principles that identify general practice with the provision of personal, individualised and co-ordinated care. The older principles appear to be threatened by the weight of new initiatives and the changes that have been required in order to support them.

The need for teamwork in public sector organisations including health services has steadily gained credibility as a way of improving productivity and quality of care and the research base showing links between team working and effectiveness is growing. The concept of a team has several key features. They share a common purpose and goals, they are task oriented, but with different and complementary skills (Hayes, 1997). To function effectively they will have a shared knowledge base, and collective responsibility and they will regularly interact with each other, usually through formal or informal team meetings (West and Slater, 1996). Evaluative research in such settings though, often shows a lack of congruence in staff interpretation of teamwork with compromised communication and limited opportunities for understanding of roles and for team learning (Freeman *et al.*, 2000).

Like teams described elsewhere in the National Health Service (Freeman *et al.*, 2000; Ross *et al.*, 2000) the health care professionals featured in this thesis shared some, but not all characteristics of a group of people that might be designated a team. Information exchange between health care professionals could be poor, there was little evidence of formal meetings to discuss the overall needs of clients and individual healthcare workers could be over-focused on tasks, while lacking understanding of the ultimate purpose of their interventions. Overall, the involvement of general practitioners, district and specialist nurses and community pharmacists in joint working might be better described as a multidisciplinary collaboration (Rink *et al.*, 2000), with opportunities for building quality of care through more team focused activity.

Research on working with hospitals has tended to focus on communication issues, which were also a strong theme in this work. For example, studies have consistently shown that a proportion of patients are in contact with their general practitioner before discharge information is received (Penny, 1988; Mageean, 1986; Foster *et al.*, 2002). Studies looking at information needs of general practitioners have found that information on why medicines are altered in hospital was one of the biggest needs (Brackenborough, 1997; Al-Rashed *et al.*, 2001a; Al-Rashed *et al.*, 2001b). Some research has been published on power relations between general practitioners and consultants, mainly in relation to the notion of the primary care led National Health Service (Evans, 1996), but materials on joint working and sharing responsibility are

almost entirely guidance or discussion documents rather than original research (Pearson, 1999; Weiner *et al.*, 2005; Stille *et al.*, 2005).

Good relationships amongst clinicians are essential for patient care. The interface between primary and secondary care is an arena that can have a crucial bearing on the effectiveness, safety and efficiency of care. However, taking referral practice as an example, behaviours and expectations can vary enormously both on the side of the referring and the receiving doctor and there has been little research to identify which particular model is likely to deliver the highest quality care. In the absence of guiding principles, establishing agreement depends on communication, yet communication across the interface, which is greatly researched, has improved little through sequential studies over forty years. Despite the huge traffic of patients across the interface and the implications of this traffic for patients and for healthcare economies, the interface remains an under researched area in healthcare sociology and healthcare policy.

7.3.5 Implications for clinical governance

The concept of clinical governance was introduced in 1998 where it was at the centre of a ten year improvement programme directed towards reducing variation in care and improving overall standards (Department of Health, 1997; Department of Health, 1998). Key elements included the implementation of evidence, assuring standards, reducing risk, involving patients, supporting education and training within a framework that would assure accountability in the delivery of clinical services.

Clinical governance in general practice has been considered weak when compared against structures and processes that may be in place in other areas of healthcare (National Audit Office, 2007). The approach has been heavily weighted towards educational approaches to quality improvement, including the use of clinical guidelines, this notwithstanding the recent introduction of the Qualities and Outcomes Framework to general practice, which is increasingly viewed as a standards based performance management tool. Although there is an appreciation of risks associated with many aspects of general practice and the associated interactions of general practitioners with the primary care team and/or specialists, there is little associated

theoretical knowledge around the generation of hazards and how they might be averted. Research into safety critical functions and continuing development and testing of process, procedure and design is urgently needed in general practice. These aspects of risk management are underrepresented and need to be incorporated and assured in clinical governance frameworks.

7.4 CONCLUSIONS

There are a range of methods for the investigation and analysis of critical incidents in healthcare that are more or less applicable in different situations and which have different performance characteristics in relation to their likely validity, accuracy and potential for impact on quality and safety of care. It is possible to draw some contrasts between methods that are based on assessment of large numbers of events, using self reporting or audit type approaches and others that focus in depth on single or small clusters of events. Amongst those that are suitable for the investigation of single or small clusters of events, root cause analysis and organisational accidents causation models using a human factors approach had the strongest performance characteristics.

Application of a depth investigative method using a human factors framework in primary care supports the generalisation of the approach across health care settings. The approach is explanatory, and provides opportunities for learning about people and processes in healthcare systems and how they interact. Classical qualitative approaches may be used in analysing interviews adding insights of a different kind when applied to the same materials.

Medication-related admissions in older people is an important issue because of associated morbidity and unnecessary health care costs. Using an epidemiological approach it was possible to assess the scale of the problem and to illustrate how age, gender, case complexity and polypharmacy could predict the likelihood of medication related problems or medication related admissions due to under-treatment, adverse reactions or over treatment. This form of study also generates a sampling frame for depth investigations involving patients who have suffered an adverse event.

Investigation of such cases provides a "window on the health care system" (Vincent *et al.*, 1999), documenting not only how things go wrong, but also identifying why.

Case studies of patients with preventable medication related admissions illustrate how the interplay of patient and staff factors, communication issues and system problems acted together to create the circumstances underpinning failings in the management of care. The context of these quality problems could be summarised as relating to general practice as an organisational form in transition, to the multi-professional model of working that characterises the extended primary care "team" and to the interface with secondary care that continues to present an interpretative gap exacerbated by limited communication media.

Many of the factors that contribute to medication management problems are understood and clinical governance in general practice builds on strong foundations. The improvement agenda should address the three domains identified in this study to support and develop safety culture in general practice settings. Continuing development and assured integrity of general practice systems is required along with improvements in processes and systems to assure more effective working with other community staff and with secondary care colleagues.

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Appendix 1

Literature terms used to search MEDLINE, including hit rate

Search Term	Number of hits
Human factors method* and (english in la)	2
Accident investigation and (english in la)	19
Incident investigation and (english in la)	7
Accident analysis and (english in la)	11
Incident analysis and (english in la)	15
Management Oversight & Risk Tree (english in la)	5
Tripod Beta and (english in la)	0
Tripod Delta and (english in la)	0
Root cause analysis and (english in la)	12
Barrier analysis and (english in la)	3 hits, but none relevant
Change Analysis and (english in la)	16 hits, but relating to changes at the cell level
Human reliability analysis and (english in la)	1
Task analysis and (english in la)	5791 hits. Inspected the first 100 records. None related to medical accidents
Influence diagram approach and (english in la)	0
Sequentially timed events plotting and (english in la)	0
Intelligent Safety Assistant and (english in la)	58 hits, but none relevant
Multilinear events sequencing and (english in la)	0
Technic of operations review and (english in la)	1 record in domain of occupational health
Hazard and Operability Study and (english in la)	0
Critical incident technique and (english in la)	24
Accident evolution and barrier function model and (english in la)	1 record relating to occupational health
Object – Z and (english in la)	0

Appendix 2

Search Summary

The identification of publications featuring methods for the investigation of critical incidents in healthcare

The search strategy is a *modification* of the classic search for systematic review based on crossing concepts.

We identified **3 concepts, which** we felt would be featured in publications for examination:

Concept A – methods of enquiry, investigation or analysis

Concept B – errors, omissions or mistakes

Concept C – incident(s) or adverse event(s) in clinical care

Searching on **Concept A** *OR* **Concept B** *OR* **Concept C** generated large numbers of citations, but in our view was too low in specificity to be of value

Searching on **Concept A** *AND* **Concept B** *AND* **Concept C** generated a small number of citations, but in our view was too low in sensitivity to be of value.

Searching on **(Concept A** *AND* **Concept B)** *OR* **(Concept A** *AND* **Concept C)** *OR* **(Concept B** *AND* **Concept C)** generated a manageable number of citations which in our view was likely to be of high sensitivity and reasonable specificity.

For each concept we aimed to be as comprehensive as possible, by including both thesaurus terms and free text terms.

The final search was constructed as follows:

**Concept A: methods of enquiry, investigation or analysis*

1 4922 "RISK-MANAGEMENT"/ without-subheadings , methods , organization-and-administration , statistics-and-numerical-data

2 1236 "SAFETY-MANAGEMENT"/ without-subheadings , methods , organization-and-administration , statistics-and-numerical-data

3 2709 "ACCIDENT PREVENTION"/ without-subheadings , methods , organization-and-administration , statistics-and-numerical-data

4 933 explode "EQUIPMENT FAILURE ANALYSIS"/ALL SUBHEADINGS

5 7102 explode "TASK-PERFORMANCE-AND-ANALYSIS"/ ALL SUBHEADINGS

6 598 explode "SENTINEL SURVEILLANCE"/ALL SUBHEADINGS

7 5663 explode "MODELS,-ORGANIZATIONAL"/ALL SUBHEADINGS

8 8604 explode "SYSTEMS ANALYSIS"/ALL SUBHEADINGS

9 1488 explode "CRITICAL-PATHWAYS"/ALL SUBHEADINGS

10 13612 (RISK MANAGEMENT) OR (SAFETY MANAGEMENT) OR (ACCIDENT PREVENTION)

11 1240 (ACCIDENT INVESTIGATION*) OR (ACCIDENT ANALYS*)

12 934 (EQUIPMENT FAILURE INVESTIGATION*) OR (EQUIPMENT FAILURE ANALYS*)

13 5530 (TASK PERFORMANCE INVESTIGATION*) OR (TASK PERFORMANCE ANALYS*)

14 6491 (SENTINEL SURVEILLANCE) OR (ORGANI?ATIONAL MODEL*)

15 2385 (SYSTEMS ANALYS*) OR (CRITICAL PATHWAY* ANALYS*)

16 3 (SIGNIFICANT EVENT AUDIT) OR (SIGNIFICANT EVENT ANALYS*)

17 137 (INCIDENT INVESTIGATION) OR (INCIDENT ANALYSIS) OR (CRITICAL INCIDENT TECHNI*)

18 154 (CONFIDENTIAL ENQUIR*) OR (CONFIDENTIAL INQUIR*)

19 25 (PUBLIC ENQUIR*) OR (PUBLIC INQUIR*)

20 28 (ROOT CAUSE INVESTIGAT*) OR (ROOT CAUSE ANALYS*) OR (ROOT CAUSE TECHN*)

21 32 (HUMAN FACTOR* INVESTIGAT*) OR (HUMAN FACTOR* TECHN*) OR (HUMAN FACTOR* ANALYS*)

22 38485 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21

****Concept B: errors, omission or mistakes*

23 25731 explode "MEDICAL-ERRORS"/ without-subheadings , adverse-effects , classification , mortality , methods , nursing , prevention-and-control , psychology , statistics-and-numerical-data

24 3936 explode "IATROGENIC-DISEASE"/ without-subheadings , epidemiology , prevention-and-control

25 16293 (MEDICAL or SURGICAL or OBSTETRIC or NURSING or ANAESTHETIC or SURGICAL or MEDICATION or DIAGNOSTIC) near2 (ERROR$ or MISTAKE*)

26 4305 IATROGENIC near2 (DISEAS* or ILLNESS*)

27 30675 #23 or #24 or #25 or #26

****Concept C: incidents or adverse events in clinical care*

28 1531 (MEDICAL or SURGICAL or OBSTETRIC or NURSING or CLINICAL or ANAESTHETIC or SURGICAL or MEDICATION or DIAGNOSTIC) near2 (ACCIDENT? or INCIDENT? or INJURY?)

29 4662 (ADVERSE or UNTOWARD or UNWANTED) near2 (OUTCOME? or OCCURRENCE?)

30 14911 (ADVERSE or CRITICAL or SIGNIFICANT or UNTOWARD or UNWANTED) near2 (INCIDENT? or EVENT?)

31 27115 (UNTOWARD or UNEXPECTED or MATERNAL or PERINATAL or NEONATAL or INFANT or PADIATRIC or PEDIATRIC ORPERIOPERATIVE OR SURGICAL OR DIABETIC OR ASTHMA) NEAR2 (DEATH* OR MORTALITY)

32 47267 #28 or #29 or #30 or #31

****Concept (A+B) or (B+C) or (A+C)*

33 968 #22 and #27

34 734 #22 and #32

35 567 #27 and #32

** 36 1961 #33 or #34 or #35**

Appendix 3

Screening Form

PUBREF_____

Author _____ **Year** _____ **Journal**_____

Screened by: ☐ SR ☐ MW

Screening Criteria:

Yes	No	
☐	☐	The paper features one or more **critical incidents**
☐	☐	The critical incident is one in which a **patient** suffered or could have suffered an adverse outcome
☐	☐	The critical incident occurred in a **health care** setting
☐	☐	A **retrospective enquiry** into the incident took place
☐	☐	The enquiry included **investigation of error** or possible error
☐	☐	The paper is a **description or critique** of relevant method

Decision:

- ☐ Investigation of error in health care
- ☐ Method or critique
- ☐ Drop
  - ☐ No patient outcome
  - ☐ Not retrospective
  - ☐ No investigation
  - ☐ Other:
- ☐ Not clear (discuss)

Comments

_____

_____

_____

_____

_____

_____

Appendix 4

Appraisal Form

PUBREF _____

Author _____ **Year** _____ **Journal** _____

Appraised by: ☐ SR ☐ MW

If more than one response is applicable to any question, then tick all relevant boxes

A. DETAILS OF THE APPRAISED PUBLICATION

1. Country Setting
- ☐ [1] Multi-national
- ☐ [2] UK
- ☐ [3] Europe
- ☐ [4] Australasia
- ☐ [5] N America
- ☐ [6] Africa
- ☐ [7] Asia
- ☐ [8] other _____
- ☐ [9] not clear

2. Level of care
- ☐ [1] primary or community care
- ☐ [2] secondary or specialist care
- ☐ [3] pharmacy
- ☐ [4] laboratory
- ☐ [5] radiology
- ☐ [6] other _____
- ☐ [9] not clear

3. Speciality _____

4. Source of critical incidents
- ☐ [1] staff recall
- ☐ [2] participant/non participant observation
- ☐ [3] reporting system (specify)
- ☐ [31] voluntary
- ☐ [32] obligatory
- ☐ [33] statutory
- ☐
- ☐ [39] not clear
- ☐ [4] review/occurrence screening
- ☐ [5] claims/patient complaints
- ☐ [6] other_____
- ☐ [9] not clear

5. Number of critical incidents featured

_____

6. Summary description of critical incidents featured_____

7. Class of critical incidents featured
- ☐ [1] unrestricted within the named specialty
- ☐ [2] in a patient group (e.g. age, sex, ethnic group)
- ☐ [3] in a diagnostic group (e.g. asthma, pregnancy)
- ☐ [4] associated with an intervention (e.g. drug-related, associated with a surgical procedure)
- ☐ [5] with a common proximate cause
- ☐ [6] with a common contributory cause
- ☐ [7]other_____
- ☐ [9] not clear

8. Severity of critical incidents featured (injury suffered)
- ☐ [1] patient died
- ☐ [2] permanent injury
- ☐ [3] temporary injury
- ☐ [4] no injury
- ☐ [5] other_____
- ☐ [9] not clear

9. Severity of critical incidents featured (treatment required)
- ☐ [1] major intervention required
- ☐ [2] some intervention required
- ☐ [3] no intervention required
- ☐ [4] other_____
- ☐ [9] not clear

B. CONDUCT OF THE INVESTIGATION(S)

10. Agency responsible for the investigation(s)

- ☐ [1] professional organisation
- ☐ [2] healthcare institution
- ☐ [3] academic department
- ☐ [4] government or state
- ☐ [5] insurance company
- ☐ [6] legal representatives
- ☐ [7] other_____
- ☐ [9] not clear

11. Organisational relations of agency to unit investigated

- ☐ [1] internal to the healthcare unit
- ☐ [2] external to the healthcare unit
- ☐ [3] external to the organisation(s)
- ☐ [4] other_____
- ☐ [9] not clear

12. Person(s) responsible for field investigation

- ☐ [1] individual(s) reporting the incident
- ☐ [2] individual(s) designated to conduct investigation
- ☐ [21] internal to the healthcare unit
- ☐ [22] external to the healthcare unit
- ☐ [23] external to the organisation(s)
- ☐ [29] not clear
- ☐ [3] other_____
- ☐ [9] not clear

13. Profession(s) of person(s) responsible for field investigation

- ☐ [1] medical
- ☐ [2] nursing
- ☐ [3] psychology
- ☐ [4] management
- ☐ [5] other_____
- ☐ [9] not clear

14. Training/experience in accident investigation

- ☐ [1] previous experience
- ☐ [2] previous training
- ☐ [3] written guidance
- ☐ [4] other_____
- ☐ [9] not clear

15. Reference to established technique for accident investigation?

- ☐ [1] critical incident monitoring (e.g. AIMS)
- ☐ [2] critical incident method (e.g. Flanagan)
- ☐ [3] significant event auditing (e.g. Pringle)
- ☐ [4] root cause analysis (e.g. JHACO)
- ☐ [5] contributory factors models (e.g. Vincent)
- ☐ [6] audit models (e.g. CEDSI)
- ☐ [7] other _____
- ☐ [9] not clear

16. Reference to established investigative framework?

- ☐ [1] reporting systems (e.g. AIMS, MDA)
- ☐ [2] occurrence screening studies (e.g. HMPS)
- ☐ [3] population based incidence studies: patient denominator (e.g. review of 1000 operations)
- ☐ [4] population based incidence studies: process denominator (e.g. review of 1000 prescriptions)
- ☐ [5] confidential enquiry (e.g. CESDI)
- ☐ [6] medico legal investigations (e.g. MDU series)
- ☐ [7]other _____
- ☐ [9] not clear

C. DATA COLLECTION AND CAUSAL ANALYSIS

C1. INTERVIEWS AND SELF REPORTS

☐[1] Yes ☐[9] Not clear

17. Person(s) interviewed/reporting

- ☐ [1] patient
- ☐ [2] relative
- ☐ [3] staff (specify which)
- ☐ [31] administrative
- ☐ [32] medical
- ☐ [33] nursing
- ☐ [34] technical
- ☐ [35] paramedic
- ☐ [36] other _____
- ☐ [39] not clear
- ☐ [4] other _____
- ☐ [9] not clear

18. Recruitment of informants

- ☐ [1] entirely voluntary
- ☐ [2] institutional obligation
- ☐ [3] statutory obligation
- ☐ [4] other_____
- ☐ [9] not clear

19. Protection of informants

- ☐ [1] open or public enquiry
- ☐ [2] confidentiality assured
- ☐ [3] anonymity assured
- ☐ [4] protection from subpnoea
- ☐ [5] other_____
- ☐ [9] not clear

20. Interview/reporting technique(s) used

- ☐ [1] reporting (specify which)
- ☐ [11] paper based
- ☐ [12] electronic
- ☐ [19] not clear
- ☐ [2] interview (specify which)
- ☐ [21] face to face
- ☐ [22] telephone
- ☐ [29] not clear
- ☐ [3] group interview
- ☐ [4] other_____
- ☐ [9] not clear

21. Type of interview/report

- ☐ [1] narrative description
- ☐ [2] questionnaire
- ☐ [21] closed questions

continued.....

- ☐ [22] open questions
- ☐ [29] not clear
- ☐ [3] interview (specify which)
- ☐ [31] semi-structured
- ☐ [32] open interview
- ☐ [39] not clear
- ☐ [4] group interview (specify which)
- ☐ [41] nominal group
- ☐ [42] focus group
- ☐ [43] other group_____
- ☐ [49] not clear
- ☐ [5] other _____
- ☐ [9] not clear

22. Additional techniques used (interviews)

- ☐ [1] conceptual framework
- ☐ [2] explicit criteria
- ☐ [3] barrier analysis
- ☐ [4] process flow diagram
- ☐ [5] fault tree
- ☐ [6] other_____
- ☐ [9] not clear

23. Interval between incident and investigation (specify)

_____

- ☐ [9] not clear

24. Mean number of interviewees/case_____

- ☐ [9] not clear

25. Mean duration of each interview_____

- ☐ [9] not clear

26. Methods used for interview/report critique

- ☐ [1] established guidelines
- ☐ [2] conceptual framework
- ☐ [3] explicit criteria
- ☐ [4] expert opinion
- ☐ [5] other_____
- ☐ [9] not clear

27. Quality assurance: data collection

- ☐ [1] scribe accompanies interviewer
- ☐ [2] audio record/transcribed account
- ☐ [3] informant confirms account
- ☐ [4] triangulation between informants
- ☐ [5] other_____
- ☐ [9] not clear

28. Quality assurance: data critique

- ☐ [1] consensus panel
- ☐ [2] duplicate assessment and interpretative checks
- ☐ [3] inter-rater reliability documented
- ☐ [4] other _____
- ☐ [9] not clear

C2. PRIMARY DOCUMENT REVIEW

☐[1] Yes ☐[9] Not clear

29. Source of document data

- ☐ [1] medical record
- ☐ [2] prescribing record
- ☐ [3] protocol(s)
- ☐ [4] training manuals
- ☐ [5] other _____
- ☐ [9] not clear

30. Methods used for data extraction

- ☐ [1] narrative summary
- ☐ [2] data abstraction form
- ☐ [3] coding sheet/precoded
- ☐ [4] other_____
- ☐ [9] not clear

31. Interval between incident and investigation (specify)

_____

- ☐ [9] not clear

32. Time taken per document set

_____

- ☐ [9] not clear

33. Methods used for document critique

- ☐ [1] established guidelines
- ☐ [2] conceptual framework
- ☐ [3] explicit criteria
- ☐ [4] expert opinion
- ☐ [5] other_____
- ☐ [9] not clear

34. Quality assurance: data collection

- ☐ [1] duplicate abstraction and interpretative checks
- ☐ [2] inter-rater reliability documented
- ☐ [3] other _____
- ☐ [9] not clear

35. Quality assurance: data critique

- ☐ [1] consensus panel
- ☐ [2] duplicate assessment and interpretative checks
- ☐ [3] inter-rater reliability documented
- ☐ [4] other_____
- ☐ [9] not clear

3. PHYSICAL/LOGISTIC ASSESSMENT

☐[1] Yes ☐[9] Not clear

36. Source of physical/logistic data

- ☐ [1] site visit
- ☐ [2] site maps and plot plans
- ☐ [3] equipment checks
- ☐ [4] contacts with other
- ☐ [5] commercial materials
- ☐ [6] other _____
- ☐ [9] not clear

37. Observational techniques used to gather data

- ☐ [1] observation (checklist)
- ☐ [2] observation (implicit standards)
- ☐ [3] inspection (checklist)
- ☐ [4] inspection (implicit standards)
- ☐ [5] equipment testing

☐ [6] video/photographs
☐ [7] other _____
☐ [9] not clear

38. Interval between incident and investigation (specify)

_____
☐ [9] not clear

39. Time taken for assessment

_____
☐ [9] not clear

40. Methods used for judging physical/logistic aspects

☐ [1] established guidelines
☐ [2] conceptual framework
☐ [3] explicit criteria
☐ [4] expert opinion
☐ [5] other_____
☐ [9] not clear

41. Quality assurance: data collection

☐ [1] duplicate observations and interpretative checks between assessors
☐ [2] inter-rater reliability documented
☐ [3] other _____
☐ [9] not clear

42. Quality assurance: data critique

☐ [1] consensus panel
☐ [2] duplicate assessment and interpretative checks
☐ [3] inter-rater reliability documented
☐ [4] other _____
☐ [9] not clear

D. PRESENTATION AND INTERPRETATION OF DATA

43. How are the outcomes of the critical incident investigation(s) formulated

☐ [1] focus on clinical and patho-physiological issues
☐ [2] classification of different types of errors
☐ [3] elucidation of cause(s) of errors
☐ [4] other _____
☐ [9] not clear

44. Do the outcomes relate to any underlying model of accident causation?

☐ [1] active and latent failures (e.g. Reason)
☐ [2] contributory factors (e.g. CRU/ALARM)
☐ [3] chain of causation (e.g. AEB, Toxic cascade)
☐ [4] decision making models (e.g. Rasmussen)
☐ [5] other _____
☐ [9] not clear

45. How is the data synthesised

☐ [1] general discussion
☐ [2] synthesis of narrative
☐ [3] numerical summaries
☐ [4] other _____
☐ [9] not clear

46. Are recommendations made which might lead to improved patient safety?

☐ [1] discussion of methods/approach used
☐ [2] discussion of size and scope of problems
☐ [3] general suggestions for improvement
☐ [4] specific solutions based on *errors* identified
☐ [5] specific solutions based on *causes* identified
☐ [6] other _____
☐ [9] not clear

47. Implementation of changes?

- ☐ [1] no discussion of implementation
- ☐ [2] statement of intention for implementation
- ☐ [3] description of implementation of changes
- ☐ [4] implementation and *informal* evaluation
- ☐ [5] implementation and *formal* evaluation
- ☐ [6] other_____
- ☐ [9] not clear

48. Other comments

_____

_____

_____

_____

_____

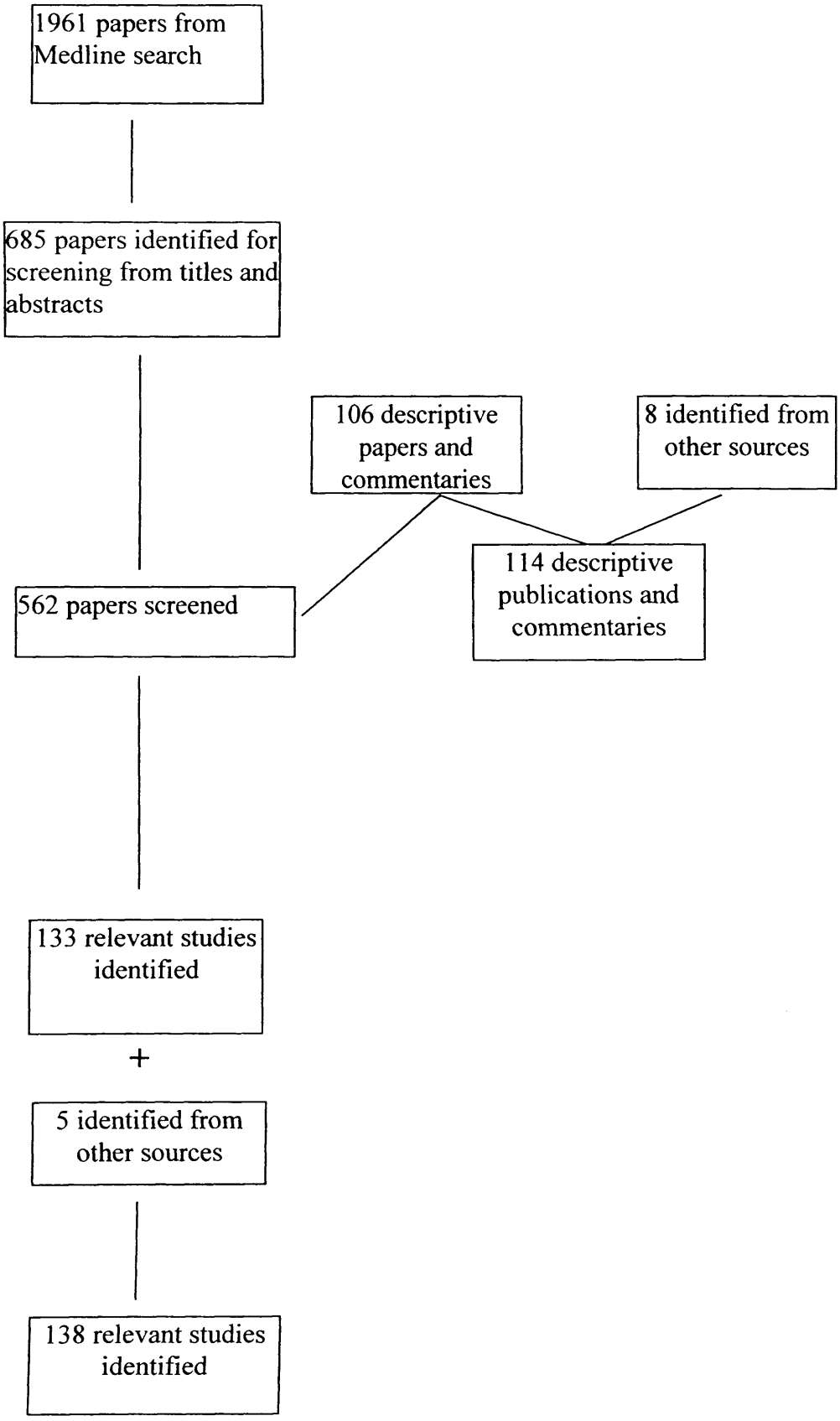
_____

_____

_____

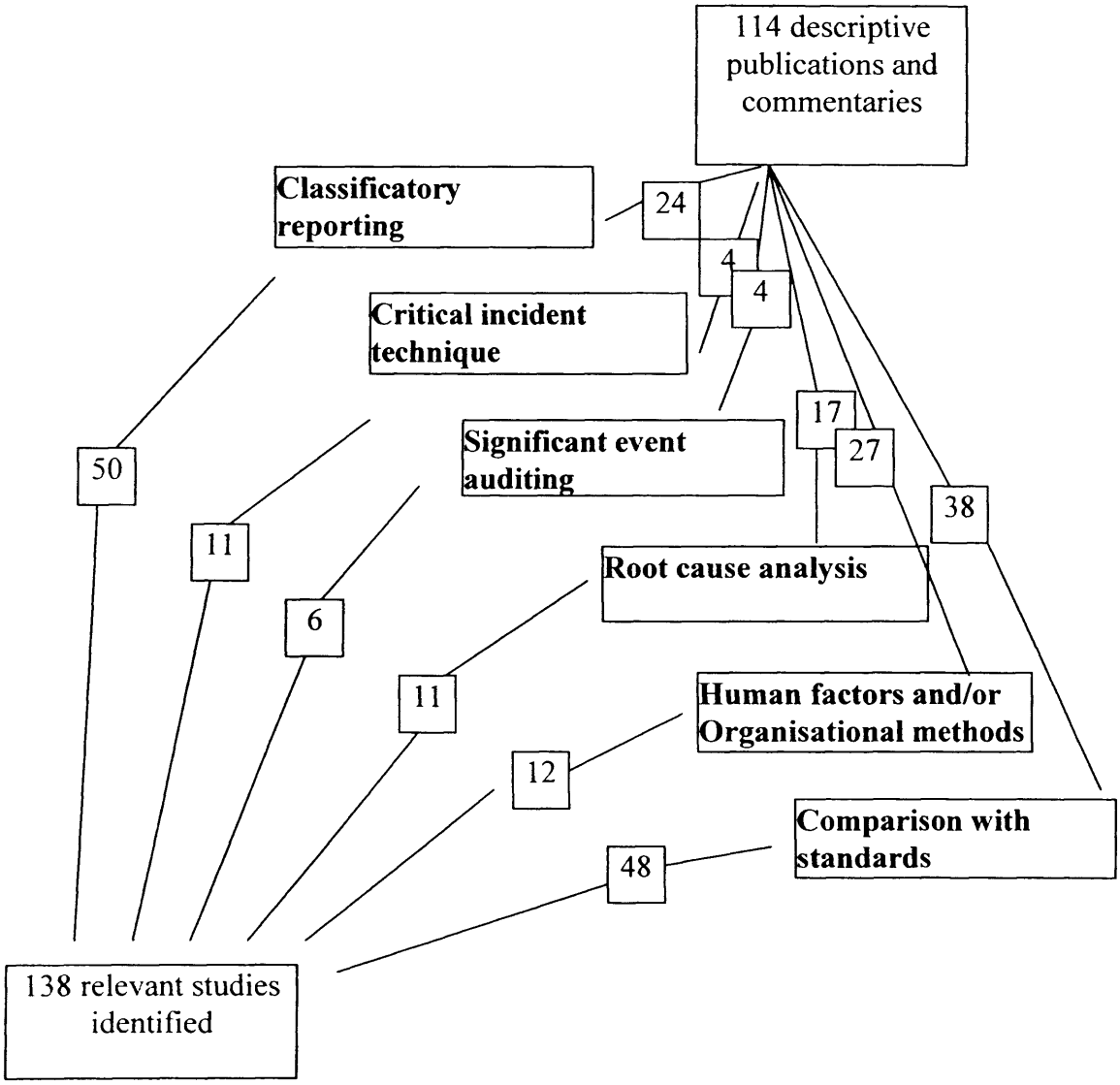
Appendix 5

Selection of relevant literature



Appendix 6

Classification of techniques in healthcare



Appendix 7

Summaries of individual techniques

Table A7:1: Summary of Individual Techniques: Classificatory Reporting (CLR)

	TECHNIQUE
Overview of CLR	Although the approach is applied in some ad hoc studies, the majority of papers describe findings of the Australian Incident Monitoring System (AIMS), which is also the most well developed example of the approach. AIMS is a national mechanism for reporting classifying and analysing data on problems arising from the delivery of healthcare. AIMS is run by the Australian Patient Safety Foundation (APSF) and was introduced in 1996 as a tool for any incident or potential incident in healthcare to be reported, using a single standard form. Speciality based pages on these forms have since been developed for anaesthesia, intensive care, emergency medicine, surgery, pathology and general practice. The AIMS report forms consist of two components: part A – a confidential incident report form; and part B – an anonymous incident monitoring section. In Part A incident information is collected at local level and is then coded using the APSF software. The coding of the information provides the means for understanding the underlying causes of the incident and for analysing the contributing factors. Part B is sent to the APSF after all identifying information is removed. This anonymous data is then entered into an aggregated database that allows all health units to receive comparative information linking their performance with other 'like' organisations. The de-identified data supports the aggregation of low frequency events at international level and is therefore very effective for identifying and co-ordinating system based strategies to better detect, manage and prevent problems.
When would technique be used	AIMS is used for any actual or potential incident or accident in healthcare.
Outputs e.g. are recommendations provided as a result of the investigation & analysis	AIMS uses a classification system of software specifically designed for 'things that go wrong' in health care. The software elicits the key features of the incident, places the event in context and records the contributing factors, both system based errors and human errors. Some of the contributing factors that are recorded are: • Management decisions • Infrastructure, working conditions • Communications, records • Staff quantity and quality • Supervision and tasking • Equipment availability and/or suitability • Policies, protocols and pathways
Positives of Technique	• The system ensures confidentiality and anonymity therefore staff are more likely to report the incident (there is some legal protection). • Identification of common factors, trends from aggregated data. • Such identification can assist to justify changes or proposals that require funding. • National and international system enables comparative data analysis
Negatives of Technique	• Data depends on that included in the forms and can not be investigated further if not already done so at local level • The level of information is dependent on the amount of detail provided by the person reporting the incident. • Only one type of data is collected and analysed – secondary documentation, giving no opportunity to check accuracy.
References	Australian Patient Safety Foundation website: http://www.apsf.net.au/ Chen PP, Ma M, Chan S, Oh TE. Incident reporting in acute pain management. *Anaesthesia* 1998; 53: 730-735.

Choy YC, Lee CY, Inbasegaran K. anaesthesia Incident monitoring Study in Kuala Lumpar Hospital; the second report. *Medical J Malaysia* 1999; 54: 4-10.

Kluger MT, Short TG. Aspiration during anasthesia: a rview of 133 cases from the Australian Anaesthetic Incident Monitoring Study (AIMS). *Anaesthesia* 1999; 54: 19-26.

Morris GP, Morris RW. Anaesthesia and fatigue: an analysis of the first 10 years of the Australian Incident Monitoring Study 1987-1997. *Anaesth. Intensive Care* 2000; 28: 300-304.

Sinclair M, Simmons S, Cyna A. Incidents in obstetric anaesthesia and analgesia: an analysis of 5000 AIMS reports. *Anaesth. Intensive Care* 1999; 27: 275-281.

Steven D, Malpass A, Moller J, Runciman WB, Helps SC. Towards safer drug use in general practice. *J. Qual. Clin. Pract.* 1999; 19: 47-50.

Vinen J. Incident monitoring in emergency departments: an Australian model. *Acad. Emerg. Med.*, 2000; 7: 1290-1297.

Table A7:2: Summary of Individual Techniques: Critical Incident Technique (CIT)

	TECHNIQUE
Overview of CIT	The critical incident technique was first described by Flanagan (1954) who described it as a set of principles for gathering data rather than a rigid set of rules. Flanagan set out a series of defined steps to collect and analyse critical incidents: specifying the aims of the work to be studied, specifying the incidents to be collected, methods of data collection, analysis and interpretation. The technique was applied to a variety of areas, mostly with the aim of describing and specifying the key skills involved in a particular kind of work, often by collecting and contrasting specific instances of skill or lack of skill. Flanagan also notes that while the procedures for collecting the factual data appear sound, methods of classification of incidents and interpretation of the findings remained relatively subjective. In healthcare a considerable number of studies refer to the critical incident technique and to Flanagan's original paper. However few make specific use of his principles and the reference to the technique sometimes seems little more than a justification for collecting information on a series of unrelated incidents. The true ancestor of most healthcare papers is Cooper's (1978) pioneering study on preventable anaesthetic mishaps. Cooper states specifically that his study is a modification of the critical incident technique. Critical incidents may be collected by a variety of methods, but are usually based on a system of voluntary reporting. Early studies (Cooper *et al.*, 1984) initially used interviews with members of staff, sometimes focussing on open questions about critical incidents and in a second phase using more targeted questions about specific types of incidents. Once staff were familiar with the method voluntary reporting was introduced. Later studies have generally relied on voluntary reporting of incidents using a questionnaire with both free text and specific questions.
When would technique be used	The most substantial and wide ranging studies have been in anaesthesia where the approach has had considerable influence. Studies have also been carried out in intensive care (Wright & Parker 1998), on deaths in general practice (Berlin *et al.*, 1992) and uncomfortable prescribing decisions (Bradley, 1992). However no other specialty has produced a sustained series of studies in which an understanding of the causes of incidents has been followed the introduction of preventative measures.
Outputs e.g. are recommendations provided as a result of the investigation & analysis	Cooper provides a table of strategies for prevention of incidents based not only on the specific clinical problems identified but also on the more general problems underlying a number of different kinds of errors.
Positives of Technique	• More easily applied than large scale epidemiological studies • Original CI studies used to develop a set of strategies for preventing recurrence • Cooper's work draws on human factors and the psychology of human error anticipating later thinking on human error in healthcare
Negatives of Technique	• Most studies give little or no information on the methods of investigation or analysis • Highly reliant on the intuition and expertise of the investigators • Technique has been very little developed since Cooper's pioneering studies
References	Berlin A, Spencer JA, Bhopal RS, van Zwanenberg TD. Audit of deaths in general practice: pilot study of the critical incident technique. *Quality in Health Care* 1992; 1: 231-235. Bradley CP. Uncomfortable prescribing decisions: a critical incident study. *BMJ* 1992; 304:294-296. Cooper JB, Newbower RA, Long CD, McPeek B. Preventable anaesthetic mishaps: a study of human

	factors. *Anesthesiology* 1978; 49: 399-406. Cooper JB, Newbower RS, Kitz RJ. An analysis of major errors and equipment failures in anaesthesia management: considerations for prevention and detection. *Anesthesiology* 1984;60:34-42 Flanagan JC. The critical incident technique. *Psychological Bulletin* 1954;51: 327-358. Anon. Critical questions; critical incidents, critical answers. *Lancet* 1988; 1373-1374. Runciman WB, Sellen A, Webb RK, Williamson JA, Currie M, Morgan C et al. Errors, incidents and accidents in anaesthetic practice. *Anaes Intens Care* 1993;21:506-519 Runciman WB, Webb RK, Lee R, Holland R. System Failure: An analysis of 2000 incident reports. *Anaes Intens Care* 1993;21: 684-695. Wright D, MacKenzie SJ, Buchan I, Cairns CS, Price LE. Critical incidents in the intensive therapy unit. *The Lancet* 1991;338: 676-678.

Table A7:3: Summary of Individual Techniques: Significant Event Audit (SEA)

	TECHNIQUE
Overview of SEA	Significant event auditing or SEA involves "audit" of a single case or event, where things went badly, or sometimes where things went well (Pringle *et al.*, 1995). SEA was not designed to address patient safety issues, but as a quality improvement technique which can be applied more generally to improving the organisation and delivery of care. Significant event audit meetings are conducted with groups of people or teams as a work based reflective activity. It is potentially anti hierarchical and the effective functioning of the participating small group is generally accepted as a prerequisite for successful significant event auditing (Robinson *et al.*, 1995). One member of the team presents the details of an incident considered significant and leads the SEA process (Westcott *et al.*, 2000) or an outsider, skilled in managing small group work, facilitates the process (Robinson *et al.*, 1995). The account of what happened is presented with assistance from clinical notes if relevant. Frameworks have been suggested to help guide the analysis of the case and leading to action points. SEA is important as a vehicle for identifying opportunities for improvement (Pringle et al., 1995), or for creating a safe environment for members of staff to share worries and concerns or to congratulate each other on good practice.
When would technique be used	SEA is widely used as an educational approach in the general practice setting in the United Kingdom, where adverse events including deaths, patient complaints or administrative mistakes may be used as a starting point for significant event auditing.
Outputs e.g. are recommendations provided as a result of the investigation & analysis	The educational value of significant event auditing (at least in well functioning and highly motivated teams with time and resources available) is not disputed, but the capacity of the significant event audit to promote improvement in practice has not as yet been demonstrated. This will depend on the links between the generation of recommendations and their implementation. In relation to improving the quality of care significant event auditing is however an information gathering strategy, not a change strategy as such.
Positives of Technique	• SEA can provide a valuable opportunity to further develop quality improvement activities in any clinical setting where there are regular meetings of work based teams. (In the absence of such meetings, changes in the organisation are required in order to proceed). • Experience shows that over time the culture and communication of teams participating in SEA can change. • It is a good screening tool for identifying problems in the quality of health care and its delivery, and in helping to set an audit agenda. • Its inclusion in a practice's audit programme balances the intellectual and the emotional content of performance review.
Negatives of Technique	• The capacity of the significant event audit to promote improvement in practice has not as yet been demonstrated. (This will depend on the links between the generation of recommendations and their implementation.) • Some clinical settings are more hierarchical than others and clinicians may be closed to the views of other members of staff. • Significant event auditing is complementary to and not a substitute for more conventional audit methods. • In relation to improving the quality of care significant event auditing is an information gathering strategy, not a change strategy as such. • In some settings SEA may simply not be acceptable.
References	Flanagan JC. The Critical Incident Technique. *Psych Bull* 1954;51: 327-358. Pringle M, Bradley CP, Carmichael CM, Wallis H, Moore A. Significant event auditing. A study of the feasibility and potential of case-based auditing in primary medical care. *Occas Pap R Coll Gen*

	Pract 1995;70:1-71. Pringle M. Preventing ischaemic heart disease in one general practice: from one patient, through clinical audit, needs assessment and commissioning into quality improvement. *BMJ* 1998; 317: 1120-1123. Robinson LA, Stacy R, Spencer JA, Bhopal RS. Use of facilitated case discussions for significant event auditing. *BMJ* 1995;311: 315-318. Westcott R, Sweeney G, Stead J. Significant Event Audit in Practice: a preliminary study. *Family Practice* 2000;17: 173-179.

Table A7:4: Summary of Individual Techniques: Root Cause Analysis (RCA)

	TECHNIQUE
Overview of RCA	Root Cause Analysis or RCA is essentially a total quality management tool. It is a systematic approach that drills down deep to identify the basic reasons for a problem – the root causes. RCA is not based on any specific theory of human error or system failure, but it does provide a toolbox of useful techniques and tools for use by incident investigators. RCA was originally developed more than 30 years ago within the industrial sector, e.g. transport, chemical and nuclear industries, as a methodology to investigate serious accidents. In healthcare, both in the US and UK, there is a huge interest in the use of RCA tools as a mechanism to investigate serious incidents. This has been fuelled by the publication of key documents such as Organisation with a Memory (DoH, 2000) in the UK and the work on RCA undertaken by the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) in the US. JCAHO provides the most comprehensive guide on how to complete a successful RCA based on 21 separate steps making it an extremely thorough approach. Examples of the 21 steps include, defining the problem, using brainstorming, TA, FMEA and Gantt Chart techniques; studying the problem; determining what happened; identifying contributing process factors and other human, equipment and environmental factors; measure, collect and assess data of proximate and underlying causes; confirm root causes; etc. Some investigators, e.g. Handley (2000) have simplified this technique and reduced RCA to just 7 steps.
When would technique be used	Since 1996 JCAHO in the US has required hospitals to use the RCA process to investigate serious incidents e.g. in-patient suicide, infant abductions and deaths related to delays in treatment. As well as the 21 step process JCAHO also outline a number of RCA tools and techniques, which can be used by the incident investigator to both, collect data and analyse the system failures. The National Patient Safety Agency (NPSA) in the UK has recently been set up to co-ordinate and enhance organisational safety learning through the investigation and analysis of serious adverse events in UK hospitals. In addition to this RCA could be used locally to investigate a critical incident or a near miss.
Outputs e.g. are recommendations provided as a result of the investigation & analysis	The analysis identifies changes that could be made in systems or processes that would improve the level of performance and reduce the risk of a particular serious adverse event occurring in the future. RCA focuses primarily on systems and processes, not individual performance; the analysis progresses from special causes in clinical processes to common causes in organisational processes; and the analysis repeatedly digs deeper by asking 'why?' questions until no additional logical answer can be identified.
Positives of Technique	• Focus in on how to improve systems rather than blaming an individual. • Helps identify system weak points. • Utilises a variety of techniques to investigate and analyse error. • Provides investigators with a complete accident methodology. • RCA if done correctly is generally quite a cost-effective methodology
Negatives of Technique	• Limited documentation exists in the healthcare sector on the range of RCA tools available and in particular worked examples showing their applicability to certain types of accident investigations. • Accident investigators must be fully trained in a variety of RCA techniques if they are to successfully analyse incidents. • RCA can be a time consuming process, if a variety of detailed techniques are used. • RCA can be very easily be made overly complicated and does not guarantee a complete answer.

References	Amo MF. Root Cause Analysis: a tool for understanding why accidents occur. *Balance,* 1998: July/August Anon. Child's death leads to new medication error policies. *Hosp Peer Rev* 1998;23:141-3,146. Berry K, Krizek B. Root Cause Analysis in Response to a Near Miss. *Journal for Healthcare Quality*, 2000;22: 16-18. Beyea SC, Nicoll LH. When an adverse sentinel event is the cause for action. *AORN Journal.* 1999;70:703-704 Department of Health, *An Organisation with a memory. Report of an expert Group on Learning from Adverse Events.* London: The Stationery Office, 2000. Handley CC. Quality improvement through root cause analysis. *Hospital Management Quarterly* 2000; 21:74-78. Hirsch KA, Wallace DT. Conduct a cost-effective RCA by brainstorming. *Hospital Peer Review* July 1999; 105–112. Joint Commission on Accreditation of Healthcare Organisations. *Root cause analysis in healthcare: Tools and Techniques.* Illinois: JCAHO, 2000.

Table A7:5: Summary of Individual Techniques: Organisational Accident Causation Model (OACM)

	TECHNIQUE
Overview of OACM	The Organisational Accident Causation Model or OACM is a category in which studies reporting analysis of incidents have been grouped together on the basis of using primarily interview techniques and applying a framework for analysis based on Reason's Organisational Accident Causation Model. The focus of this description is on Vincent et al.'s (1999) model also known as the CRU/ALARM protocol for the investigation and analysis of clinical incidents. This model is essentially a guide of how to conduct an investigation using interviews, applying a framework when gathering and analysing the data and producing recommendations for change. The framework is based on human factors literature particularly the work of Reason (1997), Rasmussen (1976, 1982) and Norman (1981). These theorists proposed their ideas as a result of studying accidents in industry, transport and the military which led to a widening of focus of the causes of error to include pre-existing organisational factors rather then limiting the focus of blame entirely on the individual. The framework is used during the interviewing process to explore the key acts that led to the adverse outcome. The framework helps the investigator to identify contributing factors such as: patient factors, (e.g. the patient's condition and co-morbidities) task design, the availability and utility of protocols, individual or staff factors (knowledge, skills and experience), team factors (e.g. communication, support and supervision), management actions or decisions (e.g. policies regarding the use of locum, or agency staff, continuing education, training and supervision and the availability of equipment and supplies) and the institutional context (e.g. financial constraints, external regulatory bodies and the broader economic and political climate).
When would technique be used	This technique is used to investigate critical incidents, adverse events and near misses. It's been used for the latter as a learning process, where the emotional impact of an adverse event isn't as great for the staff. The classification system proposed by Vincent et al has also been incorporated into the National Patient Safety Agency's adverse incident investigation and analysis tools.
Outputs e.g. are recommendations provided as a result of the investigation & analysis	During the analysis process, investigators identify the implications and action plans from each case, particularly where these are associated with general contributing factors rather than those specific to the case under investigation. The end result is a summary of the chronology, identification of all clinical management problems and the associated contributory factors, positive features of the process of care and recommended action and time scales for each general factor requiring attention.
Positives of Technique	• Focus in on how to improve systems and working environment rather than focusing blame on an individual. • Identifies a range of weakness in systems, teams and/or individuals. • Some methods provide investigators with a complete investigation tool. • Based on current accepted models of human performance
Negatives of Technique	• Some investigators have had difficulty with some terms. • Incident investigators need to be trained in human error theory if they are to truly understand error typology and translate this knowledge into practical accident

	investigation and analysis. • Models and theories have not been formally evaluated.
References	Davies JM. Application of the Winnipeg model to obstetric and neonatal audit. *Top-Health-Inf-Manage* 2000; 20(4): 12-22. Norman DA. Categorisation of Action Slips. *Psychological Review* 1981;88:1-15. Rasmussen J. Outlines of a hybrid model of the process operator. In: Sheridan TB, Johannsen G, editors. *Monitoring Behaviour and Supervisory Control*. New York: Plenum Press, 1976. Rasmussen J. Human errors: a taxonomy for describing human malfunction in industrial installations. *Journal of Occupational Accidents* 1982;4: 311-333. Reason J. *Managing the Risks of Organisational Accidents*. Ashgate, Aldershot. 1997 Stanhope N, Vincent CA, Taylor-Adams S, O'Connor A, Beard RW. Applying human factors methods to clinical risk management in obstetrics. *British Journal of Obstetrics and Gynaecology* 1997;104: 1225-1232. Vincent CA, Taylor-Adams S, Chapman EJ *et al.* A Protocol for the Investigation and Analysis of Clinical Incidents. London: University College London / Association of Litigation and Risk Management, 1999

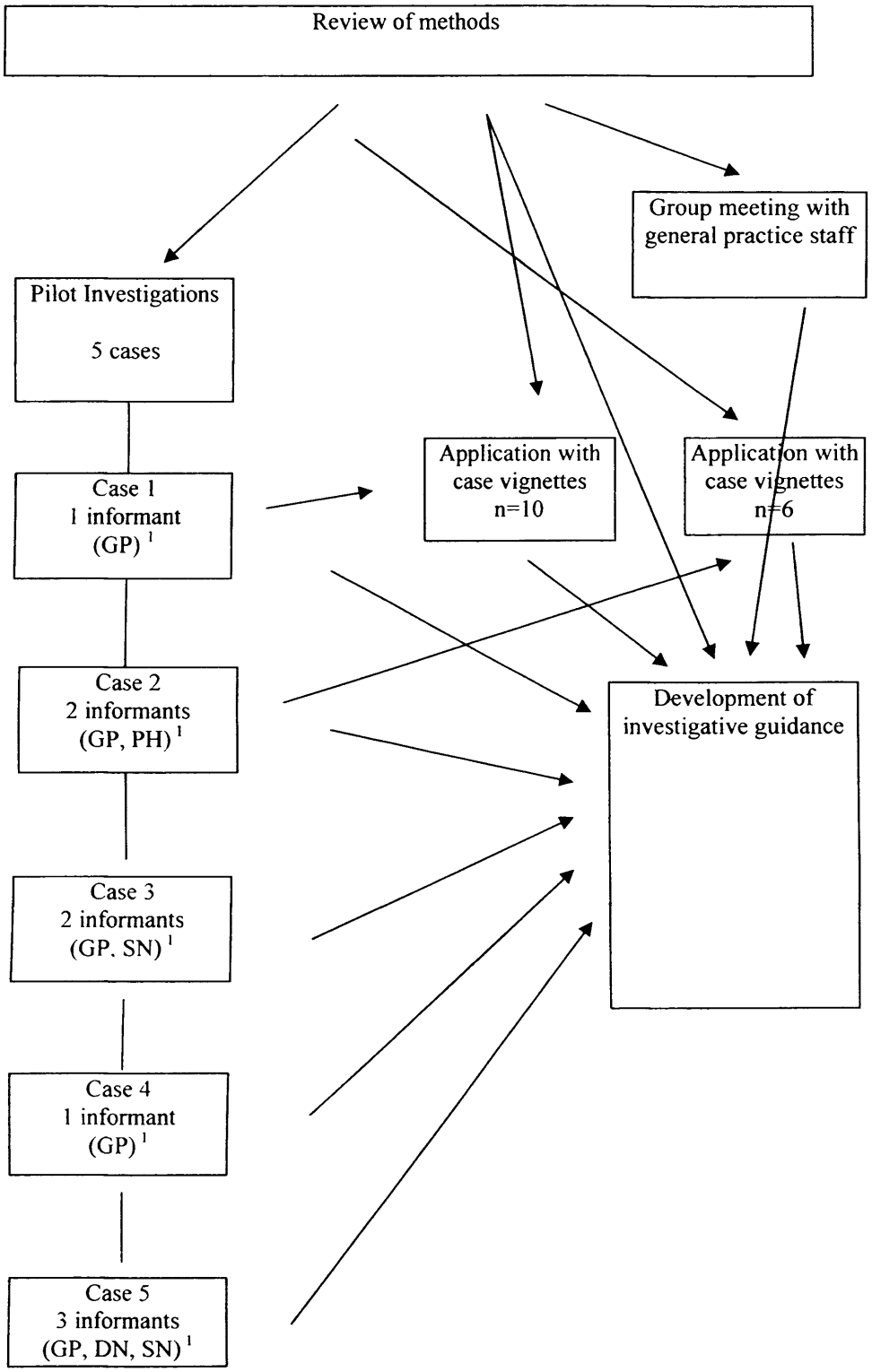
Table A7:6: Summary of Individual Techniques: Comparison with Standards (CWS)

	TECHNIQUE
Overview of CWS approach	The comparison with standards method or CWS is extremely broad. The application of the approach to maternal deaths preceded the institutionalisation of audit as a quality improvement technique in other areas of health care. The underlying theoretical assumption is that healthcare staff and healthcare managers generally want to perform well, but have little appreciation of the standard of their own performance. Typically efforts are made to identify all incidents of interest (usually deaths) in a defined population over a defined time period, using statutory reporting systems, voluntary notification (especially enquiries into perinatal mortality) and through additional hospital and community based enquiries. Medical records are examined, but this approach was also supplemented by questionnaire enquiries or interviews with health care staff or relatives. The information assembled was then appraised against implicit or explicit standards for care of such patients. A panel of experts typically conducts the appraisal, and results are presented as levels of performance against expectation.
When would technique be used	The majority of confidential enquiries are into maternal, perinatal or post operative deaths or suicides. Other examples include stroke deaths in a single locality asthma deaths reviewed by an expert or speciality group.
Outputs e.g. are recommendations provided as a result of the investigation & analysis	Although data is generally presented as numerical summaries, occasionally vignettes of individual cases may be presented or more depth insights will be alluded to within published papers. There is some potential for confidential enquiries to incorporate both clinical and organisational issues in a systematic way, though there is little sign of this to date.
Positives of Technique	• Confidential approach and voluntary participation were reassuring for clinicians who might worry about professional credibility and litigation • Close involvement of professional organisations helps to endorse ownership by participants and to institutionalise involvement without the need for statute • Complete ascertainment of cases improves generalisability of findings and for many events and enables meaningful links to be made with denominator populations at risk of the adverse outcome. • Use of standardised data collection methods enables comparable data collection across sites and over time • Analysis at regional as well as local level promotes local review and implementation of change
Negatives of Technique	• Only feasible to conduct serial confidential enquiries for a relatively small number of adverse outcomes of significant public health importance • Can be used to assemble data on structural and process issues of relevance to patient safety, but study design reduces scope for emergent findings • Historically have tended to focus more on clinical activity, rather than contextual issues, which might determine patient safety. • Findings of confidential enquiries still remote from individual cases and influence on implementation of change mainly through dissemination of findings through professional organisations and scientific literature
References	Burr ML, Davies BH, Hoare A, Jones A, Williamson IJ, Holgate SK *et al.* A confidential enquiry into asthma deaths in Wales. *Thorax* 1999;54:985-9 Cartlidge PH, Jones HP, Stewart JH, Drayton MR, Ferguson DS, Matthes JW *et al.* Confidential enquiry into deaths due to prematurity. *Acta Paediatrica* 1999; 88:220-3

	Drife J. Maternal mortality: lessons from the confidential enquiry. *Hosp Med* 1999; 60: 156-157. Thomson C. The confidential inquiry comes of age. *Br J Psychiatry* 1999:175:302. Walker GJ, Ashley DE, McCaw AM, Bernard GW. Maternal mortality in Jamaica. *Lancet* 1986;1:486-488

Appendix 8

Development of investigative method for primary care



[1] GP = general practitioner; PH = pharmacist; SN = specialist nurse; DN = district nurse

Appendix 9

GUIDANCE FOR PRIMARY CARE INVESTIGATIONS

Introduction

The great majority of care in the National Health Service is of a very high clinical standard and avoidable adverse outcomes involving patients are uncommon in relation to the high volume of care provided every day in hospitals and in the community. Yet, when patients do suffer in the course of care, this can have serious consequences for the patients concerned, for their families, for the health care staff involved and for public confidence in the National Health Service. Failures of care often display strong similarities to incidents that have occurred before, in some cases almost exactly replicating them. Also near misses (where patients in potentially hazardous predicaments are saved by an intervention), which occur far more often than adverse events, seem to be underpinned by the same circumstances as their more serious counterparts. Various initiatives to record and investigate clinical incidents and near misses are motivated by the knowledge that recurrences might be avoided if the lessons of experience were properly learned across the National Health Service.

This guidance is prepared for professionals in the primary care sector who wish to learn from clinical incidents occurring in their own setting. The core materials comprise formal, practical guidance for investigating and analysing clinical incidents. The guidance adopts a *systems approach*. The key feature of the approach is that it takes any investigation beyond questions of who did what "wrong". The approach moves on to identify factors in the consulting room, in practice administrative systems, in staff relations, in the work environment, and in the policy environment, which ultimately influence how health professions deal with their day to day work. The approach has intuitive appeal for health workers who have always recognised the importance of the context in which they work, on the decisions they take and the way they behave. Furthermore, the approach leads to a variety of possible action points which are broader and more imaginative than any suggestions which could emerge from an enquiry which focuses only on the actions or omissions of individual health workers.

The guidance is restricted to the process of investigation and analysis of clinical incidents. We have not been prescriptive about how incidents should be identified or which should be investigated. We believe that the approach can be adapted to the situation in which it is applied. In some practices the practice manager or an individual doctor may wish to speak individually to various staff involved with an incident. In others, the approach might be applied in a group meeting, as an alternative to a rather less structured significant event audit. We do

believe however, that decisions and actions following inquiries would be more effective if grounded in a thorough and systematic investigation and analysis of the initial circumstance. We hope that you will find the contents of the pack instructive and useful, and that our guidance and materials provide a useful framework for assembling and organising your observations on the delivery of care in your own setting. Moreover, we hope you find the approach useful in identifying areas in your own setting that might be changed for the better on behalf of the patients for whom you care.

Why you might find the guidance useful

The guidance does not attempt to supplant clinical expertise or deny the importance of the reflections of individual clinicians on an incident. Rather the aim is to utilise clinical experience and expertise to the fullest extent. The guidance assists the reflective investigation process because:

- While it is sometimes straightforward to identify a particular action or omission as the immediate cause of an incident, closer analysis usually reveals a series of events leading up to this. The identification of a possible departure from good practice is usually only the very first step of the investigation.

- A structured and systematic approach means that the ground to be covered in any investigation is, to a significant extent, already mapped out. The guidance can help to ensure a comprehensive inquiry and leads naturally to the production of useful reports when these are needed.

- The methods used are designed to promote a greater climate of openness and to move away from finger pointing and the routine assignation of blame. The guidance ensures that a full range of factors which might contribute to an incident are considered, prevents premature conclusions being drawn and avoids routine assignment of blame

- As the guidance provides for a structured and consistent approach, members of staff who might be questioned will find the process less threatening than traditional unstructured approaches. Also, the process of assembling and interpreting contributory factors is closely linked and the rationale for any recommendations is explicit and self evident from the findings of the enquiry.

- The sequence of narrative account, problems identified, then contributing factors lays out the entire context in which a clinical incident or near miss occurs. Presenting such findings in a suitable report form is a small step from writing up the findings of an inquiry.

The main additional work that might be expected would be to reflect on the findings and to identify feasible changes that might be implemented to make a difference.

Investigating incidents in your setting

Clinical incidents and near misses

A clinical incident is something that happened to a patient, a clinical outcome probably with harmful or potentially harmful effects. More common than clinical incidents in primary care are near misses. These are cases where patients were at risk of a clinical outcome probably harmful or potentially harmful, but something happened, evolved, or was instituted which successfully saved them from an adverse outcome. Near misses are the kinds of incidents where one rather thinks, "thank goodness, that might have been serious". It is often said that exceptional positive outcomes should be recognised as opportunities for learning as well as unfortunate adverse outcomes. Certainly exceptional positive outcomes are an opportunity for congratulation, though it is not established that these are as influential in bringing about learning. There seems to be something about looking at adverse outcomes that makes the learning stick. Positive outcomes are to be expected; negative outcomes are to be avoided if at all possible.

Administrative failures in the primary care setting are not uncommon. Missing test results, mislaid referral letters and messages that never arrive are typical examples. Undoubtedly these are areas that need attention, and will emerge as contributory factors in investigations of clinical incidents. These might be raised as areas for discussion in improving the practice environment, but if the staff feel comfortable enough to start with situations where the risk to a patient was consequential, or might have been consequential, then even greater learning can take place.

It is acknowledged that staff may be the victims of incidents in healthcare settings. For example abuse from patients, needle stick injuries, accidents on the premises. While such incidents are important and deserve investigation, the purpose of this guidance is not to investigate incidents involving staff, but to deal with factors that might put patient safety at risk. The principles for investigating incidents in which staff are the victims are likely to be similar to those for investigating incidents were patients are victims. Nevertheless, health and safety for staff is a sufficiently important that it should probably be given separate attention.

Which incidents should be investigated?

There is no tradition of collating or reporting incidents in primary care, so individual practices will need to decide how they identify incidents for study. It is not necessary to set up a formal surveillance or reporting system, but in some practices groundwork might be required so that individual members of staff begin to acknowledge that sometimes things go wrong and to see clinical incidents as opportunities for learning. Only a minority of incidents will need to be analysed in detail in any practice. Broadly speaking the incident will either be investigated because of its seriousness for the patient because of its potential for learning, or for building more general understanding of causes of clinical incidents. There is much to be said for investigating a `near miss' or well handled incidents, as these are less emotive and are not generally open to external scrutiny. Such `lesser' incidents may be just as fruitful in terms of `organisational learning'.

Who should investigate?

While every experienced clinician should be able to investigate clinical incidents from the perspective of clinical practice, following systematic guidance is likely to bring additional benefits in terms of comprehensiveness and investigation expertise. The practice manager might have a lot to offer and in some practices, the practice manager might work alongside a lead clinician. Early experience with the guidance has indicated that some training and experience is necessary before it can be used to its full effectiveness. Primary Care Trusts are increasingly funding training opportunities, or have access to trained facilitators who will be prepared to support a practice based enquiry. Alternatively trying out the approach and reflecting on progress with a colleague or GP tutor, is a more self directed approach. Sharing findings with colleagues is a good way to share experience and to improve the quality and so the learning opportunities from investigations.

Preparing staff for inquiries

Both the guidance and the concepts underlying it shift attention from individual members of staff to more general organisational issues. Rather than seeking to assign blame, the emphasis is on better understanding of the systemic and organisational factors that can predispose to adverse outcomes. A number of simple measures will help ensure that the process of the inquiry is constructive and non-threatening for the individuals involved. Firstly, the context and nature of the inquiry must be transparent and understood by practice partners and staff. Secondly confidentiality must be assured for patients at the centre of inquiries and for staff contributing information. Thirdly, the summary findings of the inquiry must be shared with the practice partners to seek views on their face validity. Finally, the implications of the findings for possible improvements should be made explicit and ways of tackling problems should be discussed.

Reviewing case records

Accounts of an incident may be taken from written reports of staff members, case notes or interviews with staff. The analysis may be limited if only written reports are considered, in that it may not be possible to explore the full range of conditions that allowed the event to occur. The guidance incorporates analyses from both interviews and records and assumes that much important material can only be gained from interviews. It is possible, if there is no other option, to carry out a less detailed and inevitably more superficial analysis from the case records alone. The input of an expert clinician in the area will be essential, however, if those involved in the incident are not available to be interviewed. Case records in primary care are often brief, sometimes serving as no more than an aide memoire to an individual general practitioner, or as a basic record for consultations with practice partners. Sometimes important information (e.g. drug records, allergies) is recorded electronically on the computer, but not in the notes, and sometimes the reverse. Additional information required to reconstruct chronologies might also be found in message books or nursing records. In practice, it is likely that investigations will be heavily dependent on the reports of interviewees, who themselves might require access to case records to reconstruct events.

Undertaking Interviews

In more serious incidents and where staff are not used to discussing clinical incidents in groups, interviews with individuals should be undertaken in private and, if at all possible, away from the immediate place of work in a relaxed setting. The purpose of interviews is simply to find out what happened and this should be explained at the outset. The style adopted should be supportive and understanding, and not judgmental or confrontational. Where it becomes clear that a professional shortcoming has occurred, this should be allowed to emerge naturally from the conversation, and should not be extracted by cross examination. Errors and mistakes in clinical care are rarely wilful and most staff are genuinely disturbed when it becomes clear that something they have done has contributed to an incident. Adverse comment and judgement at this stage is most unhelpful as it leads to demoralisation and defensiveness. The guidance includes an explicit framework for exploring contributory factors with informants. Underlying or contributory factors inevitably emerge in the early stages of a discussion, but are best "parked" at this stage. The informants' ideas should be valued, but it is important to ensure that all possible care management problems are identified at the outset. The systematic application of the framework thereafter is an important stage for informants as it is at this stage that the positioning of an incident against systems and organisational issues is likely to become most clear.

The overall process

The overall process is straightforward and logical, though the stages should not be treated as rigid pathways. Informants will want to provide information early on that is more relevant to later stages, and important information about earlier stages might emerge to towards the end of an interview. The map of the overall process is nevertheless useful and will need to be returned to avoid getting "lost" as detail emerges. Returning to the guidance also avoids premature conclusions being drawn about perceived contributory factors emerging early in the enquiry.

The first task is to establish a narrative or story of exactly what happened, then to identify instances where acts or omissions influenced or might have influenced events. The third task is to systematically check out possible contributory factors of relevance to the care management problems identified. Then finally to assemble the material and consider possible action points for change.

Establishing the story

Documenting exactly what happened in the care of a patient is the first task that needs to be completed. There are two aspects to be considered. Firstly the timeframe, or time window of the enquiry and secondly the range of sources of information which might be pursued.

The most useful `frame' for the investigation may not be immediately apparent. The investigator needs to take a pragmatic look at the problem and decide what time scale is to be the focus of immediate attention, while accepting that a longer and more complex story might unfold. The final outcome for the patient may be long after the period when problems in their care occurred. For instance a delayed diagnosis of cancer may result, two year's later, in the patient's death. The patient may attend for multiple appointments in both hospital and primary care settings in the last two years of their life. However the focus of an investigation would probably be between the time when symptoms were, in retrospect, clearly apparent and the time the diagnosis was eventually made. On the other hand, if a patient suffered a serious, but avoidable drug reaction, the time frame for examination might be much shorter; the interval between the prescription being issued or requested and the time the drug reaction became evident.

QUICK SUMMARY

The core of the process is to ask: What happened? How did it happen? Why did it happen? What can we learn from this and what changes should we make, if any?

What happened? - Establishing the Chronology and Outcome

The first step is simply to produce an agreed chronology of events, identifying any important areas of disagreement between accounts or between the case notes and the memories of the staff. The first part of the chronology will be dependent on the nature and time frame of the condition being investigated, but normally the focus of inquiry would be on recent events, when informants might still be expected to give reliable stories.

How did it happen? - Identifying the Care Management Problems

The next stage is to identify the key care management problems. These may be provided by the staff themselves or from the investigators' own reflections on the case. The investigator should ensure that all the care management problems are specific actions or omissions on the part of staff, rather than more general observations on the quality of care, which should be recorded elsewhere. It is easy to note down 'poor teamwork' as a care management problem, which may be a correct description of the team but should properly be recorded elsewhere as a contributory factor.

Why did it happen? - Identifying the Contributory Factors

The next step is to attempt to specify the conditions associated with each of the clinical management problems, using the framework as a guide and as a way of reflecting on the many factors that may affect the clinical process. Interviews with staff will already have provided lists of both specific and general contributory factors. Where these conflict it may be necessary to make a judgement as to the most important causes of the events. Each care management problem may be associated with several factors at different levels of the framework that were implicated in its occurrence (e.g. poor motivation (Individual), lack of supervision (Team), inadequate training policy (Organisation and Management)).

A separate analysis should be carried out for each care management problem, though the depth and detail of the contributory factors identified may vary for each. Remember to clearly distinguish specific contributory factors, which describe the reasons for the care management problem on that particular occasion, from general contributory factors that are judged to be more longstanding features of the individual, team or working conditions. Factors that are specific to an occasion and do not reflect more general problems probably have no long-term implications for the quality and safety of practice and therefore probably do not require action or changes of any kind.

There is a range of sources of information, which might be relevant. Case records are an important starting point, but in the primary care setting recollections of various individuals involved in the care of the patient are likely to be invaluable. The detail needs to be written down; what people remember as well as what is recorded elsewhere. Sometimes it becomes clear that sources of information outside the practice might be important (e.g. records at the deputising service, results held at a hospital radiology service, or recorded contacts with a patient at an early pregnancy diagnostic unit. Pragmatism is often required. Certain sources of information might be less easily accessible to primary care staff, even though they might offer learning points and represent an important stage in the genesis of an adverse outcome. The

classic example of this might be an overnight stay in hospital, or an outpatient consultation, where information has not been passed between the hospital setting and primary care. This administrative failure might have been relevant to the genesis of an adverse event for the patient, but is not likely to be amenable to change unless the relevant hospital staff are engaged in and party to the enquiry.

Possible sources of information to help assemble the patients' story

- Patients notes, including consultant letters
- Practice message book and other internal communications
- Written complaints and associated correspondence
- Discussions with staff involved with a case
- Interviews and consultations with patient and family

Identifying possible problems

The role of members of individual staff in the incident will need to be clear, including the limits of their involvement. Once the chronology of events is clear, members of staff should be asked to identify the main care management problems as they see them, without concerning themselves about whether or not anyone is or is not to blame for any of them. The aim will be to identify all important acts or omissions made by staff, or other breakdowns in the clinical process, that were (with hindsight) important points in the chain of events leading to the adverse outcome. Clinicians, and other healthcare staff, whether those involved or those advising, will have an implicit knowledge of the clinical process, as it should ideally occur, allowing for acceptable levels of variation and fluctuation. Where there are disagreements as to whether a particular action or omission is acceptable, these should be recorded. If guidelines, protocols or pathways specify clinical practice, it may be possible to identify major departures with some precision. Generally however there will be a degree of acceptable variation in practice. It will be important to look for points in the sequence of events when care went outside acceptable limits. The way possible problems are specified and the language used to describe possible problems will be important. It is possible to state that individuals were unsuccessful in achieving expected tasks, without implying incompetence or lack of care.

Problem statements in a case of wrong prescription

- The first doctor gave the patient the wrong prescription
- The pharmacist dispensed an incorrect prescription
- The receptionist did not pass the patient's query to the doctor concerned

The next stage is required to understand why individuals behaved the way they did and in most cases incompetence will prove to be an inadequate or inappropriate explanation.

Identifying contributory factors

This third phase is where the system approach to investigating incidents becomes clear and illuminating. For each possible problem identified, staff members involved should be asked to reflect on factors that they feel might have been influential or contributory with respect the behaviour observed. A framework is provided, which helps interviewers, and staff think through the various levels at which contextual factors might affect the behaviours of individuals. Although the framework has higher level, organisational factors at the top it may be more natural in clinical terms to begin by enquiring about patients factors, then moving up the table through task factors, individual, team and so on. In practice the discussion may range over many of these in any order, in which case it is simply a matter of checking through at the end to make sure all aspects have been covered. As contributory factors are identified, it is also useful to try and establish whether the factors are general or specific factors. General factors will apply to the work situation on a more or less daily basis, while specific, or one off factors are those which seem to have emerged only in relation to the case being investigated. A further aspect of contributory factors will be the potential for change. For example, a problem associated with a the way a practice handles its repeat prescriptions may be tackled by the practice, but problems generated by increasing patient demand or prescribing budgets will need to be tackled at a different level.

Contributory factors:

- Patient factors
- Individual staff factors
- Task factors
- Team factors
- Organisation and management
- Institutional setting

General contributory factors are features of the work environment operating on a day to day basis; specific contributory factors seem to apply only to the case investigated

Terms and essential concepts

Clinical incidents and near misses.

A clinical incident is something that happened to a patient, a clinical outcome probably with harmful or potentially harmful effects. More common than clinical incidents in primary care are near misses. These are cases where patients were at risk of a clinical outcome probably harmful or potentially harmful, but something happened, evolved, or was instituted which successfully saved them from an adverse outcome.

Care management problems

The first step in any analysis is to identify the `care management problems'. Care management problems are actions or omissions by staff in the process of care. Care management problems have two essential features. Firstly, the care deviated beyond safe limits of practice and secondly, the deviation had a direct or indirect effect on the eventual adverse outcome for the patient. (In cases where the impact on the patient is unclear it is sufficient that the care management problem had a potentially adverse effect).

Contributory Factors

Having identified the care management problems, the investigator then considers the factors affecting the processes or interactions and the wider organisational context. Any combination of these might contribute to the occurrence of a single care management problem. Once the investigator has identified the various factors that contributed to the incident, a further distinction needs to be drawn between specific contributory and general contributory factors. Specific factors are relevant only to that particular case on that particular occasion while general contributory factors are more enduring characteristics of individuals, teams or organisations, etc.

A framework for the analysis of incidents

The framework of factors appearing in this document is based on a framework developed for use in acute settings (Vincent et al 1999) now modified for use in primary care. The essential concepts remain the same, but the specific subheadings differ in some respects. The purpose of the framework is, broadly speaking, to define the conditions of safe and unsafe practice that may predispose to care management problems. We anticipate that this primary care framework will evolve and be modified in the light of experience with case analyses and a review of the relevant research literature.

Framework of Factors Influencing Clinical Practice in Primary Care

FACTOR TYPES	INFLUENCING CONTRIBUTORY FACTORS
Patient Factors	Condition (complexity & seriousness) Language and communication Personality and social factors
Individual (staff) Factors	Knowledge and skills Competence Physical and mental health
Task Factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results
Team Factors	Verbal communication Written communication Supervision and seeking help Team structure (consistency, leadership, etc)
Work Environment Factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support
Organisational and Management Factors	Financial resources & constraints Organisational structure Policy standards and goals Safety culture and priorities
Institutional context	Economic and regulatory context National health service executive Social and media influence Educational and professional organisations

At the top of the framework are 'patient factors'. In any clinical situation the patient's condition will have the most direct influence on practice and outcome. Other patient factors, such as personality, language and any disability may also be important as they can influence communication with staff, and hence the probability of an incident.

Further down the framework are individual (staff) and team factors. Individual factors include the knowledge, skills and experience of each member of staff, which will obviously affect their clinical practice. Each staff member is part of a team within the practice or community unit, and also part of the wider organisation of the community services in the area. The way an individual practices, and their impact on the patient, is constrained and influenced by other members of the practice or community team and the way they communicate, support and supervise each other. The team is influenced in turn by management actions and by decisions made at a higher level in the organisation. These include policies regarding the use of locum or agency staff, continuing education, training and supervision and the availability of equipment and supplies. The organisation itself is affected by the institutional context, including financial constraints, external regulatory bodies and the broader economic and political climate.

Each level of analysis can be expanded to provide a more detailed specification of the components of the major factors. For example, 'Team factors' includes items on verbal communication between receptionist, practice nurse and doctor; the quality of written communication such as the availability, quality and legibility of notes, and the availability of supervision and support. The framework provides the conceptual basis for analysing adverse incidents. It includes both the clinical factors and the higher level, organisational factors that may be influential. In doing so, it allows the whole range of possible influences to be considered and can therefore be used to guide the investigation and analysis of an incident.

Once the investigator has identified the various factors that contributed to the incident, a further distinction needs to be drawn between specific contributory factors and general conditions. That is the investigator should differentiate between those contributory factors that are only relevant on that particular occasion and those which are longstanding or permanent features of the practice, or in some cases of a member of staff. For example there might be a failure of communication between a general practitioner and a district nurse contributing to a care management problem. If this is unusual and seldom occurs otherwise, then it is a specific contributory factor, but one with no more general implications. If, on the other hand, this problem is quite frequent then the investigator would also want to note a general contributory factor of "poor communication" which would have clear implications for the safe and effective delivery of patient care.

Preparing a report

Once the interviews and analysis are completed making a report drawing together all the information available is an important discipline. The report will comprise a composite of all case material and interviews, detailing the whole incident from start to finish. Staff involved, their roles and their involvement with the incident should be included (refer to staff by grade and initials only). In the process of undertaking the interviews new care management problems may have been identified. These will need to be included in the list of care management problems. If the interviews suggest a need to follow up anything with a particular member of staff, then often it is useful to go back and use the same structured process, but concentrating on the new care management problems. The original documents can be updated to take account of this.

If the guidance is followed systematically and the interview and analysis conducted thoroughly the report and the implications of the findings should emerge from the analysis in a relatively straightforward fashion. When the composite is complete, there should be a clear view of the incident, the circumstances which led up to it, and the flaws in the care process. The contributory factors, general and specific, will be identified and linked to each care management problem. The report should then consider what implications this incident has for

the organisation. This section will summarise the general contributory factors and the implications for action. The lessons learnt can be drawn out and action plans to deal with the problems which occurred can then be formulated. Actions can usefully be directed towards addressing changes in individuals, tasks, teams, work settings, or organisational management. It is necessary to specify what is to be done, by whom, how it is to be done, and by when. This kind of action plan would then be reviewed and the effects of actions taken evaluated to check for impact. An executive summary of the case, care management problems, contributory factors and recommended actions might usefully be included as a suitable synopsis.

Example: Delayed diagnosis of septic arthritis

Mrs K was a 79-year-old widow who lived alone in a ground floor council flat. She was of Greek Cypriot extraction and spoke poor English. Communication difficulties were exacerbated by her tendency to speak fast and to get agitated or angry when she could not make herself understood. The patient had some genuine health problems, but tended to overstate the severity of her symptoms. She lived independently, but was rather lonely and isolated. She had a daughter who lived and worked 7 or 8 miles away and called in once per week.

The patient had suffered with osteoarthritis of the knees for years. She was prescribed regular analgesia and had been treated by a physiotherapist, but without perceiving any benefit. She had been referred for an orthopaedic opinion. The daughter who was having difficulty meeting her mother's needs, took her to A&E for advice. The patient was admitted and assessed, then readmitted her a week later for a total knee replacement. She developed pyrexia after the operation and was discharged on antibiotics. A week after discharge, the daughter called the district nurses office because she was unhappy about the state of the patients' knee.

One of the district nurse team visited. The patient's knee was hot and red and the wound was oozing. This was cleaned and dressed. On a second visit the nurse decided thought there had been some improvement. The patient was told to ring the doctor if she was not satisfied with progress over the following 48 hours. The patient called the following afternoon, but the on call doctor had difficulty understanding the patient's account of her problems. He said he would arrange for a visit after speaking with the district nurse. The patient called again the next day. After a short discussion with the attending nurse, the on-call doctor decided the patient should be admitted immediately to hospital.

The patient was found to have an MRSA infection of the knee joint. Arthroscopic washout was tried but was not effective. Eight days after admission she went back to theatre for open washout and debridement of the wound. The patient developed a pulmonary embolism when on the ward. She was treated with intravenous vancomycin for 20 days, and with rifampicin and trimethoprim for four weeks. She spent a total of 22 days in hospital and needed to continue warfarin for 6 months after discharge.

Chronology

29.4.99 - Patient referred for assessment by orthopaedic surgeon.
06.2.00 - Patient admitted with severe OA
15.2.00. - Patient discharged
20.2.00. - Patient admitted for L TKR.
25.2.00. – Patient discharged
04.3.00 - District nurses review following call from daughter; "wound infection"
06.3.00 - Second district nurse visit; patient told to contact the doctor
06.3.00 - Discharge note arrived; pyrexial on ward, discharged on antibiotics
07.3.00 - Call for home visit from patient; home visit deferred
08.3.00 - Second call for home visit; ambulance called and re-admitted
30.3.00 – Discharged following extended stay with septic arthritis and pulmonary embolism

ACTIVE PROBLEMS 1 OF 3

The patient was admitted to hospital for a knee replacement but neither GP nor district nurse knew this was happening.

CLINICAL CONTEXT: Patient complaining of intractable knee pain taken to A&E by her daughter. Patient admitted for assessment and respite. Seen by orthopaedic surgeon who booked patient to his operating list for an early TKR.

Patient factors	Patient not coping with pain well (S) Daughter not in a position to offer practical help and support (S)
Individual factors	Orthopaedic surgeon judged urgent need for TKR (S)
Task factors	Orthopaedic surgeon in position to influence waiting times (G)
Team factors	Discharge note very brief: indicated "OA knees, for TKR", but no dates (G/S)
Work environment factors	Not known
Organisational management and Institutional factors.	Communication between primary and secondary care is a perennial issue (G) NHS under funding and associated efficiency measures influence waits for booked admissions (G)

(S) Specific contributory factor (G) General contributory factor (M) Mitigating factor

ACTIVE PROBLEMS 2 OF 3

The primary care team were not prepared for the patient's discharge

CLINICAL CONTEXT: Patient was discharged home with antibiotics on account of postoperative pyrexia. The patient was elderly and lived alone. Neither district nurse, nor GP were contacted at time of discharge. Patient's daughter raised alarm with district nurses office. A hospital discharge letter arrived a few days later.

Patient factors	The daughter was visiting her mother and was concerned about her knee wound (M)
Individual factors	Not known
Task factors	Patient discharged on antibiotics without ascertaining cause of infection (S)
Team factors	No call from ward to indicate need for district nurse input (S) Discharge letter arrived nine days after discharge (G)
Work environment factors	Not known
Organisational management and Institutional factors.	Communication between primary and secondary care is a perennial issue (G) NHS under funding and associated efficiency measures influence bed management (G)

(S) Specific contributory factor (G) General contributory factor (M) Mitigating factor

ACTIVE PROBLEMS 3 OF 3

There was delay in recognising the seriousness of the patient's complaint

CLINICAL CONTEXT: Patient was discharged home with antibiotics. The nurse was reassured by an apparent improvement between the first and second visit, and left the patient to arrange for medical review. The patient telephoned the surgery, but a home visit was deferred. The patient was admitted directly to hospital when the full details of her condition were realised on the following day.

Patient factors	The patient was not able to make her worries and concerns clear to the first on-call GP (S)

Individual factors	The visiting nurse did not recognise the significance of the hot red joint (S)
Task factors	The visiting nurse assumed that the antibiotics prescribed by the hospital were for the patient's "wound infection" (S) The first on-call GP did not visit the patient immediately (S)
Team factors	The visiting nurse did not discuss case with any of the doctors (S)
Work environment factors	The visiting nurse was a staff grade nurse seconded to the team on account of staffing shortages (G) The G grade district nurse was on holiday and supervisory arrangement were unclear (S) Communication between district nurse team and general practitioners is left to the initiative of staff (G)
Organisational management and Institutional factors.	Shortage of district nursing staff (G) Removal of obligation on GPs to visit (G)

(S) Specific contributory factor (G) General contributory factor (M) Mitigating factor

Actions for consideration
Individuals: Consider possible learning needs of visiting district nurse and review in context of annual appraisal
Tasks: Hospital based review of clinical issues around investigation and discharge of patients with postoperative pyrexia of unknown origin; general practice based review of policy and practice on home visits
Teams: reinforce hospital policy of telephoning community staff on discharge of elderly patients from hospital; review operation of discharge communications and consider faxing details on day of discharge
Work environment: Nurse managers to review policy for staffing and supervisory arrangements to assure that overall levels of staffing are not compromised by sickness or

study leave absence; district nurse and general practitioners to discuss and implement means of assuring more effective and communication between the two staff groups
Organisational management and Institutional: Improve incentives for recruitment and retention of district nursing staff; target hospital-primary care communication as an area for development and evaluation

Appendix 10

Occurrence Screening Checklist

DATE:

GENERAL PRACTITIONER:

Patient details

SURNAME **INITIALS** **DOB**

HOSPITAL NO: **ADMISSION DATE:**

ADMISSION DIAGNOSIS:

PAST MEDICAL HISTORY: **DRUG HISTORY:**

COMMENTS:

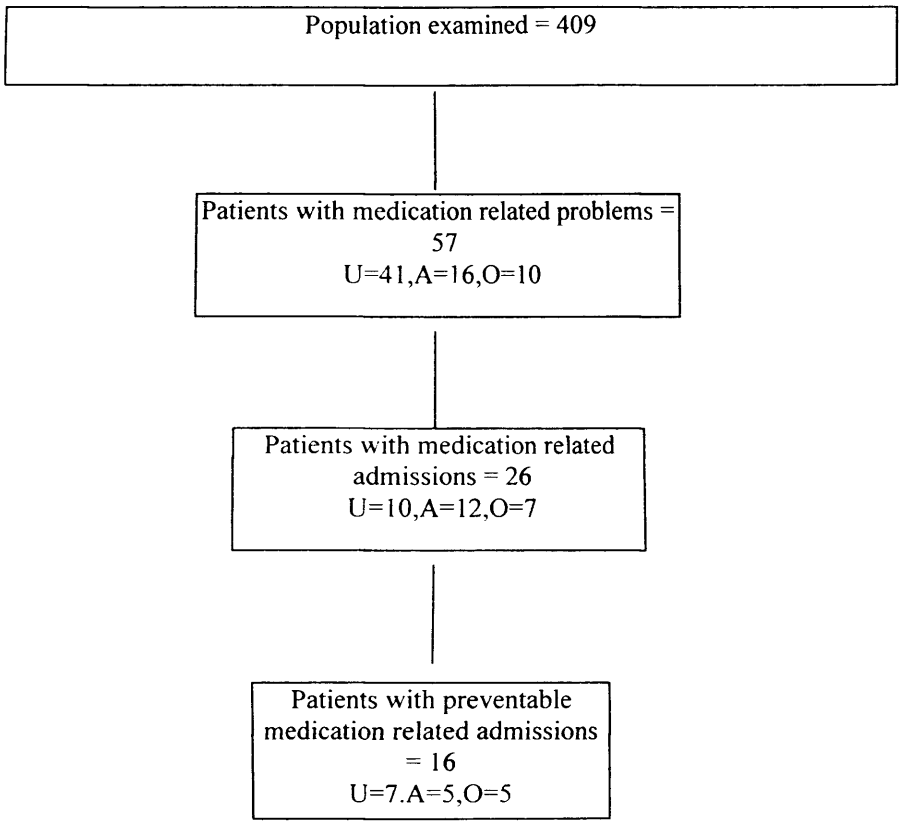
SCREENING CRITERIA (AFTER STRAND ET AL, 1990)	YES	NO
The patient has a medical condition that requires drug therapy, but the patient is not receiving the drug		
The patient has a medical condition for which the wrong drug is being taken		
The patient has a medical condition for which too little of the correct drug is being taken		
The patient has a medical condition for which too much of the correct drug is being taken		
The patient has a condition resulting from an adverse drug reaction		
The patient has a condition resulting from a drug-drug or drug-food reaction		
The patient has a condition that is the result of not receiving a prescribed drug		
The patient has a condition that is the result of taking a drug for which there is no valid medical indication		

MEDICATION PROBLEM CONTRIBUTORY YES MAYBE NO

MEDICATION PROBLEM PREVENTABLE **YES** **MAYBE** **NO**

Appendix 11

Flow chart for cases detected in the occurrence screening study



U=Undertreatment,; A=Adverse reaction; O=Overtreatment

Appendix 12

Patient information sheet and Consent Form

Letterhead

Towards safe and effective medication management in older people.

We are undertaking research to understand what kinds of problems can occur in the prescription, dispensing, administration and monitoring of medications for older people. We would like to ask you to help us in this. The following information tells you about our study and what we would ask of you if you decide to participate.

Problems with medications

Patients are prescribed medicines in an attempt to remove symptoms, to improve the quality of life and, in some cases, to increase anticipated life span. However, medicines can themselves cause unwanted health problems. Sometimes this is because of known and unavoidable side effects. On other occasions, doses may be too low or too high, or a medicine may not be the best one for the particular patient. Also, some patients become ill because they fail to take the prescribed course of treatment that would have helped them.

The Government is urging health workers and social care staff to make sure that patients get the maximum benefit from their medication, with the minimum of problems. We have been funded by the National Health Service Executive to identify the different kinds of problems can occur in the prescription, dispensing, administration and monitoring of medications, to find out why such problems occur and to make recommendations for improvements.

The study

Pharmacy and medical staff at the ****** Hospital are reviewing all new patients in order to identify those in whom some sort of problem with medications might have contributed to the admission. We believe we can learn a great deal about medication management by investigating the circumstances that led to a patient having a medication related problem. We would like to talk with patients, their doctors, their pharmacist, community nurse, and any other helpers, to get a clear picture of how

medications are organised and to learn whether anyone thinks that things might be done differently. The study is research, and not linked to trying to find out if individual people can be blamed for anything. Rather, the focus is on the systems and procedures in place to help ensure safe and effective medication management, and ways of making things better.

We aim to assemble information from different patients, and from this we will try to identify common problems and underlying reasons for problems with medications. A report of this research with recommendations will be made available to local health and social care services and to those participants who would like copies. Articles will be also be written for professional health and social care journals, to share what we have learnt to a wider audience. We hope this will contribute to improving health care for older people.

The help we would like from patients

We have identified you as a patient where problems with your medications might have contributed to your admission to hospital.

We would like to ask you to help us by:

1. talking to us about the medications you have been taking, any problems you have experienced in taking the medication and any help you have in taking medications
2. agreeing that we can talk to your general practitioner, local pharmacist who dispenses your medication, and district nurse and carer (if these people help you) about your medications and any help you receive in taking them and
3. agreeing that we can discuss your case with colleagues working on the project

Information about any problems you experienced with medications will, with your permission be shared with your GP and the other professionals involved in your care, as this will help us learn together what might be done better. The information we collect will be summarised in a report, but no individual will be identifiable in the report of this research , and the identities of participants will remain confidential to the research team.

If you have questions or would like to know more about the study you can ask Dr Wilson, or Dr Rogers whose contact details are given below

You do not have to take part in the study if you do not want to.

If you do decide to take part and change your mind, you may withdraw at any time without having to give a reason.

Your decision to take part will not affect your care and management in any way.

The research has been reviewed by the local research ethics committee

CONSENT FORM

TOWARDS SAFE AND EFFECTIVE MEDICATION MANAGEMENT IN OLDER PEOPLE.

To be completed by the patient:

1. I have read the information sheet about this study
2. I have had the opportunity to ask questions and discuss the study
3. I have received satisfactory answers to all my questions
4. I have received sufficient information about this study
5. I understand that I am free to withdraw from this study at any time, without giving a reason for withdrawing, without this affecting my future care
6. Do you agree to take part in this study?

Signed.....Date.....

NAME IN BLOCK CAPITALS

Witness.....Date.....

NAME IN BLOCK CAPITALS

Signature of investigator.....

Appendix 13

TOWARDS SAFE AND EFFECTIVE MEDICATION MANAGEMENT IN OLDER PEOPLE

Letterhead

CONFIDENTIAL

Interview conducted on / /

PATIENT INTERVIEW

A. PATIENT DETAILS

Name:_____ **D.O.B.** [ ] **Hospital N°** [ ] **Study N°.** [ ]

Name and address (if known) of GP

Past Medical History / Diagnosis

Patient lives

Alone ☐ With spouse or partner ☐ With friends / relatives ☐
Sheltered housing ☐ Care home ☐ Other _____

Nationality [ ] **First Language** [ ]

Interpreter Yes ☐ **No** ☐

B. MEDICATION TAKEN

1. What prescription medication are you currently taking?

Name of medication	Dose	Name of medication	Dose

2. Who prescribed this medication for you? *(Please tick all that apply)*
GP ☐ Hospital Consultant ☐ Other *(please specify)*_____

3. Has this changed in the last 3 months?
No ☐
Yes ☐

Details

4. Do you have a repeat prescription for any of these medicines? No ☐ Yes ☐

5. (If yes to question 4) Have you ever experienced any problems in ordering a repeat prescription?
No ☐
Yes ☐

Details

6. (If yes to question 4) Have you ever experienced any problems in receiving a repeat prescription?

No ☐

Yes ☐

Details

7. Have you bought (or has anyone else bought for you) any non-prescription medicines within the last 3 months?

No ☐ Yes ☐

Name of medication	Dose / Frequency of use	Name of medication	Dose / Frequency of use

C. COLLECTING YOUR MEDICINE

1. Does the same pharmacy dispense all your prescriptions? No ☐ Yes ☐

2. Do you collect your own prescriptions? No ☐ Yes ☐

3. If no to question 2. Who collects your prescription for you?

Relative ☐ Friend ☐ Home carer ☐ Pharmacy service ☐

Other (please state)_____

4. Have you (or the person who routinely collects your prescriptions) had problems collecting your medicine?

No ☐

Yes ☐

Details

D. TAKING YOUR MEDICINE

1. Have you been given instructions about how to take your medicines?

No ☐

Yes ☐

Details

2. Do you know why you have to take the medicines you have been prescribed?

No ☐

Yes ☐

Details

3. Please briefly describe how and when you take your medicines

Details

4. Do you need any assistance to take your medicines? No ☐ Yes ☐

5. If yes to question 4. Who helps you to take your medicines? Please tick all that apply.
Relative ☐ Friend ☐ Home carer ☐ Community Nurse ☐

Other (please state)_____

6. Some people encounter problems when taking their medicines. Have you experienced any of the following problems? Please tick all that apply. [Probe]

Helper not available to give assistance ☐
Problems swallowing tablets ☐
Forgetting to take medicines ☐
No problems encountered ☐
Problems taking medicines from container ☐
Difficulty in reading labels ☐
Other_____

Further comments

Appendix 14

Letterhead

Date.....

Dear Dr

Towards safe and effective medication management in older people

We are writing to invite you to participate in a study that will be of direct benefit to you and your patients. It is designed to provide new information that will guide the development and implementation of strategies to optimise medication management, reduce morbidity and unnecessary admissions in this vulnerable group

The study has three objectives:

1. To identify elderly patients admitted to the **** Hospital whose admission might be attributable to medication related problems.
2. To ascertain these patients' experiences of taking medication and any problems they encountered.
3. To determine the views of health care professionals on the factors contributing to medication related problems.

The research uses a critical incident approach to elucidate the possible factors contributing to each patient's problem. Further details are provided in the *Information Sheet* enclosed with this letter.

One of your patients has been identified by the screening process and has given their consent to contact you regarding this project. We would value your views on the factors you feel might have contributed to their medication-related problem and would like to interview you about their case. A *Case Synopsis* and *Patient Consent Form* are provided for your information. The interview would take between 30 and 60 minutes of your time and would be conducted at a time and place most convenient to you.

We would like to emphasise that this enquiry is confidential, entirely non judgmental and directed towards building a shared understanding of factors that might constrain the safety and quality of prescribing in the elderly. It is not an audit of your clinical practice, although the research team would be happy to provide a summary of their findings, which might be of interest and value as evidence of clinical governance activity. In addition, participation in this study would represent work done to meet National Service Framework for Older People objectives.

Our interviewer, will telephone in the next few days to request an opportunity to meet you. Of course, participation is voluntary, and if you do not wish to be contacted please return the slip in the reply paid envelope enclosed.

Yours sincerely,

***
General Practitioner

***
Consultant Physician

Encl

Appendix 15

Letterhead

CASE SUMMARY- CONFIDENTIAL

TOWARDS SAFE AND EFFECTIVE MEDICATION MANAGEMENT IN OLDER PEOPLE

CASE SUMMARY SHEET FOR GPS

PATIENT DETAILS

Name | **Date of Birth**

Previous Medical History

Social Circumstances

ADMISSION DETAILS

Circumstances of admission

Date of Admission | **Date of Discharge** | **Hospital Number**

Diagnosis

MEDICATION DETAILS

Medication	Dose	Comments

Medications taken as prescribed Yes ☐ No ☐

Patient reported medication changes Yes ☐ No ☐